I-128

From: smwilkin@ralcorp.com

Sent: Friday, October 13, 2006 1:54 PM

To: WICHQ-SFPD

Cc: lmmullen@ralcorp.com; tlburche@ralcorp.com

Subject: Docket ID Number 0584-AD77, WIC Food Packages Rule

Attachments: Ralston Foods WIC Food Packages Comments.doc

The attached document is in reference to Docket ID Number 0584-AD77, "WIC Food Packages Rule". Ralston Foods respectfully submits the following comments:

(See attached file: Ralston Foods WIC Food Packages Comments.doc)

Suzanne M. Wilkinson Ralston Foods

P: 314/877-7018 F: 314/877-7771

E: smwilkin@ralcorp.com

COMMENTS ON THE WIC PROPOSED REGULATIONS

Ralcorp Holdings, Inc., a manufacturer of a variety of food products including certain products qualified for the WIC program produced by its Ralston Foods division ("Ralston Foods"), respectfully submits the following comments with regard to the proposed rule published by the USDA in the Federal Register of August 7, 2006 ("Proposed Rules") which would revise certain regulations governing the WIC program. USDA has indicated in the Overview section of the Proposed Rules that in issuing the Proposed Rules it has followed the recommendations of the U.S. Institute of Medicine in a recently issued report entitled "WIC Food Package – Time for a Change," and that USDA thinks that, compared to the current WIC package, the Proposed Rules

- Are more consistent with the US Dietary Guidelines for Americans,
- Support improved nutrient intake,
- Address emerging public health nutrition-related issues (adult and childhood obesity),
- Reinforce nutritional education messages provided to participants, and
- Provide appeal to diverse populations

Ralston Foods commends USDA's efforts to revise the WIC program to attempt to address these issues. Since Ralston Foods has served as a supplier of breakfast cereals for WIC participants, we would like to offer the following comments and suggestions with respect to the Proposed Rules as they apply to breakfast cereals.

Ralston Foods has noted with concern that the Proposed Rules would require that, in addition to meeting past criteria to qualify for participation in the WIC program, breakfast cereals would in the future also have to contain not less than 51% whole grains as established by the test set forth in the FDA's "Health Claim Notification for Whole Grain Foods With Moderate Fat Content" ("Fiber Standard"). Such a wholesale adoption of a significant whole grain content standard would appear to be somewhat inconsistent with what the Agency has identified as the purposes being served by the Proposed Rules, and we are concerned that such a standard, applied as proposed, could have unintended consequences and prove to be counter productive with respect to the total diets of WIC's participants.

The whole grain standard set forth in the Proposed Rules would seem to effectively permit participation in the WIC program by wheat and oat-based cereals only. Because of the limited inherent fiber content of corn and rice, corn and rice-based cereals would not meet the standard. Assuming the new whole grain requirement enunciated in the Proposed Rules would have the above consequence, we believe it would have the following unfortunate effects on the WIC program:

- 1) Many consumers have a strong preference for corn and rice-based cereals, and some consumers have no interest in eating those made with wheat or oats. If the WIC program offered only wheat and oat-based cereals, it is possible that some participants will procure the available cereals but not consume them, perhaps choosing to give them to other persons. In doing so the significant nutrition delivered to consumers by the various breakfast cereals historically in the program would not be gained by such participants. (USDA appears to acknowledge this possible consequence of this proposed revision in the program at page 44850 of *Federal Register* Vol. 21, ND: 151.) Hispanics alone make up nearly 40% of the WIC population and have shown strong preferences for corn and rice-based products. (USDA makes note of this in a 2002 paper called "Hispanic American Influence on the US Food Industry.")
- 2) Some WIC participants may have food allergies to wheat and/or oats. Without corn and rice-based options available to them, they would be denied the opportunity to get the nutrition of breakfast cereals.

USDA suggested that with the publication of the Proposed Rules, it was implementing the IOM report. IOM indicated that the diet recommended in the report was going to provide to participants less of what are "bad nutrients" (saturated fats, cholesterol, total fat and sodium). Cutting out corn and rice-based cereals would not serve this purpose. The report also said that the proposed diet was "more consistent with Dietary Guidelines" by including only whole grains. However the most specific whole grain advice given by the Dietary Guidelines of 2005 and by MyPyramid is to make at least half of one's grain intake whole grain. The Dietary Guidelines did not suggest that non-whole grain products should be completely eliminated from one's diet. Rather the advice reflected normal life in which choices are available.

The report also suggested that its proposal addresses the concerns of stakeholders by making more foods available in the program. The elimination of corn and rice-based cereals would seem to be inconsistent with this point.

The elimination of corn and rice-based cereals from the program would also appear to be inconsistent with USDA's assessment of the pluses of the Proposed Rules, which it listed in the Overview section of the Federal Register document, for the following reasons:

- Dietary guidance regarding ingestion of grain products in a daily diet encourages a consumer to make half of them whole grain. Such advice appears to be an acknowledgment that nutritional benefits come from non-whole grain products as well as whole grain products and that consumers enjoy choices and may not prefer to eat only whole grain.
- It is possible that persons who don't like wheat and oat-based cereals will actually decrease nutrient intake as they elect to not include cereal in their diets (assuming the WIC program offers only wheat and oat cereals).
- There is no evidence that USDA or IOM felt that control of childhood or adult obesity would be better served by the elimination of corn and rice-based cereals from the program.

• It would not seem that the WIC program would have more appeal to diverse populations by the elimination of corn and rice-based cereals from the program.

For reasons noted above Ralston Foods feels that the WIC program would better serve its participants by not making a wholesale adoption of the whole grain standard noted in the Proposed Rules. Ralston Foods is aware of the positive dietary comments made with respect to whole grain which motivated USDA to consider use of the whole grain standard in the Proposed Rules, and this comment should not be interpreted as disputing such information. However Ralston Foods believes that the cereal component of the WIC food package has historically offered significant nutrition to participants. Therefore we propose that the USDA revise the Proposed Rules to structure a partial introduction of a whole grain standard for cereal in the WIC program by making it applicable only to wheat and oat-based products seeking authorization for the program. We believe that corn and rice-based cereals should remain in the program as long as they meet the current iron and sugar requirements. We further recommend that in the future WIC provide participants with educational information regarding the merits of whole grain.

Introduction of a whole grain component as recommended above would have the benefit of educating consumers while presenting options to them. Choice will be a fact of life on a long-term basis for any WIC participant. Keeping corn and rice-based cereal choices available to participants will assure that the significant nutrition historically enjoyed by many participants in the program through these products will remain available even as participants are invited to consider choosing to use breakfast cereals as a means of getting whole grain into their diet.

We thank the USDA for considering our comments, and we commend USDA for its dedication to the nutrition and health needs of WIC participants.

WIC Comments 100306

November 6, 2006

Patricia N. Daniels
Director. Supplemental Food Programs Division,
Food and Nutrition Service
United States Department of Agriculture
3101 Park Center Drive, Room 528,
Alexandria, Virginia 22302

VIA EMAIL

Rc: Comments on the Proposed Revisions to the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC"): Food Packages (Docket ID No. 0584-AD77, "WIC Food Packages Rule")

Dear Ms. Daniels:

The American Beverage Association welcomes the opportunity to submit comments relating to the USDA's proposed rule to revise WIC Food Packages (71 Fed. Reg. 44784, August 7, 2006).

While we support USDA's goal to revise WIC food packages to better reflect current nutrition science and dictary recommendations, we are concerned that a proposal to significantly reduce 100% fruit juice is inconsistent with USDA's stated goals of furthering healthy diets.

The ABA is the national trade organization representing the broad spectrum of companies that manufacture and distribute non-alcoholic beverages in the United States. Our members are producers, marketers and distributors of virtually every non-alcoholic refreshment beverage, including fruit juices and fruit drinks. It is on behalf of our members that we submit these comments.

First, we would like to commend the USDA and IOM report¹ for the addition of fruits and vegetables to the WIC Food Packages. We agree that the WIC program should encourage greater consumption of whole fruits and vegetables, consistent with the new Dietary Guidelines for Americans.

However, we believe that the proposal to cut the allowance for 100% juice in half is antithetical to USDA's goal of increased consumption of fruits and vegetables overall. The WIC packages should place a priority on whole fruit and vegetable consumption, as does the USDA

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¹ Institute of Medicine, WIC Food Packages: Time for a Change (2006)

food guide pyramid, while encouraging the moderate consumption of juices as a portion of whole fruit and vegetable consumption. The USDA categorizes 100% fruit juice as a fruit and permits substitution of 1 cup of juice for 1 cup of fruit while stating that consumption of whole fruits is preferable because of the increased fiber content. We believe that "moderate consumption" of juice is 6.0 fluid ounces per day for children aged 6 months to five years, which is a number that falls within the range of the American Academy of Pediatrics ("AAP") guidelines.

To be consistent with AAP guidelines, we would prefer to recommend that the WIC rules permit 100% juice, at 180 ounce per month (or approximately 6 ounces daily) for children aged 6 months to five years. However, 180 ounces does not translate easily into the marketplace, given current package sizes available in the WIC program. In order to meet a 180-ounce per month allowance, either four 46-ounce, three 64-ounce, or four 12-ounce concentrates (reconstituted to 48 ounces each) would need to be purchased.

Therefore, ABA recommends that Food Package IV be revised to 144 ounces per month. This allowance could be satisfied by the purchase of three 12-ounce concentrates (reconstituted to make 144 ounces) three 46-ounce containers (138 ounces), or two 64-ounce containers (144 ounces). This amount is 50% of the current allowance of 288 ounces. Also, 144 ounces would have less of a budget impact on the program than an increase from 128 to 180 ounces. Finally, an increase from the proposed 128 ounces to 144 ounces could partially offset the reduction in nutrition from the \$8 fresh fruit and vegetable voucher recommended by IOM to the \$6 per month voucher proposed by USDA for children.

Fruit and vegetable juices that are 100% juice serve an important role in the WIC package, as they provide a readily available economical nutritional option for WIC participants who face constraints for transportation, storage, and time. Unlike whole fruits and vegetables, 100% juices have a shelf life that permits participants to use this food daily for the full duration of the monthly food packages. Fruit juices can be an economical way to get a portion of daily fruit servings as they are typically much less expensive than whole fruits. In addition, if fruit juice offerings are substantially reduced, the result may actually be fewer total "fruit servings" in the daily diet rather than more. In other words, if the juice portions are eliminated or reduced, the substitution may not be fresh fruits, but rather, no fruit at all.

Moreover, we disagree that 100% juice consumption is linked to obesity in either children or adults, as the preponderance of scientific evidence does not support such a link.²

^{&#}x27;See, e.g., O'Connor, Yang, and Nicklas, "Beverage Intake Among Preschool Children and Its Effect On Weight Status;" Pediatrics, Vol. 118:4, e1010-e1018 (October 2006) (stating "Weight status of the child had no association with the amount of total beverages, milk, 100% fruit juice, fruit drink, or soda consumed.); Alexy, Sichert-Hellert, Kersting, Manz, and Schoch, "Fruit juice consumption and the prevalence of obesity and short stature in German preschool children: results of the DONALD study," Journal of Pediatric Gastroenterol Nutrition, Vol. 29, 343-49 (1999) (finding that "even children with repeatedly excessive fruit juice consumption [i.e., more than 12 oz/day] over three years were neither obese nor short, and their growth velocity was normal."); Newby, Peterson, et al., "Beverage consumption is not associated with changes in

Rather, we believe that 100% juices are an excellent way to add a variety of nutrients and phytonutrients into the diet. USDA should take advantage of an opportunity to teach WIC mothers that 100% fruit juice is an appropriate portion of whole fruit and vegetable consumption. To drastically reduce the amount of juice in WIC food packages inappropriately suggests that 100% juice is of poor nutritional quality, and thus misses an opportunity to educate consumers on the benefits of moderate consumption.

Recommendations

With the above in mind, we offer the following recommendations for revisions to the WIC program as it relates to 100% juice allowances:

• Children, ages 6 mos. – under 5 years. We believe it is appropriate to maintain a moderate amount of 100% fruit juice for children aged 6 months and older. As we explained above, we would ideally recommend an allowance of 6.0 fluid ounces/day (180 fl.oz/mo.) for children ages six months to under 5 years, which falls within the guidelines of the American Academy of Pediatrics recommendations. However, as discussed, 180 ounces does not translate easily into the marketplace, given current package sizes available in the WIC program. Therefore, we recommend that Food Package IV be revised to 144 ounces per month.

Moreover, the proposed rule calls for the elimination of juice for infants under 1 year. However, we agree with the American Academy of Pediatrics which allows for the introduction of fruit juice after the age of 6 months.

Need for container flexibility. We recommend that the proposed rule take into account
package sizes available in the marketplace when considering the appropriate amounts for
consumption. Often larger-sized packages are considerably less expensive so we would
recommend including these larger sizes as available for purchase.

The proposed regulation for "Food Package IV," for ages one to five, prescribes a maximum of 128 ounces of juice. This size restriction will lead to significant under-redemption of juice. Presently, regulations stipulate 276 ounces of single-strength juice and 288 ounces of reconstituted juice. See 7 CFR Part 266.10. These sizes are multiples

weight and body mass index among low-income preschool children in North Dakota," Journal of American Diet Assoc., Vol. 104:7, 1086-94 (July 2004) (stating "our results are consistent with other prospective studies that have found that fruit juice is not related to childhood obesity...Current scientific evidence does not support a positive association between fruit juice and milk consumption and obesity; hence, they may still be recommended to children in reasonable amounts because they are an important source of nutrients and energy"); and Kloben, Fruit juice consumption not related to growth among preschool-aged children enrolled in the WIC program, Journal Am. Diet Assoc., Vol 101:9:996 (September 2001) (finding no statistically significant relationship between juice consumption, obesity, and short stature in the subjects).

of 46 and 48, respectively. Moreover, single-strength juice in 46 ounce containers is the authorized container in 47 states.³ All states except for Mississippi authorize concentrates (frozen and shelf stable) that reconstitute to 48 ounces.

We urge USDA to consider maximum juice prescriptions which are even multiples of 46 and 48 ounces if delineated between single strength and reconstituted, and 48 ounces if a single value is used. These sizes are consistent with other Food Packages (Packages V and VII, with 144 ounces, and Package VI, with 96 ounces). Failure to use these sizes will limit participants to only two juice selections for single strength and concentrates, which will result in monthly under-redemptions of 36 and 32 ounce sizes respectively.

Amend the voucher program. We suggest that USDA consider amending the voucher concept for fruits and vegetables to include 100% juice. For example, USDA could provide a voucher for specific 100% fruit juices, which could help avoid disproportionate program costs. Alternatively, USDA could consider allowing WIC clients to substitute one serving of fruits and vegetables a day with 6 ounces of 100% fruit juice. Notably, such a substitution is in line with the recommendations of the Dietary Guidelines for Americans 2005 and MyPyramid.

In summary, the proposed rule's restrictions on 100% juice are unnecessary. It is important to keep in mind that fresh fruits are much more expensive than juices, especially when purchased in large sizes. Moreover, the Dietary Guidelines and the American Academy of Pediatrics both suggest that more fruit juice is acceptable for a healthy diet than the WIC proposed rule would allow. When consumed in moderation and as a portion of whole fruits and vegetables, 100% fruit juices have an important role to play in a healthy diet. We encourage USDA to use the WIC program to educate consumers about this important message.

Respectfully submitted,

Katherine W. Loatman Assistant General Counsel

American Beverage Association

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³ Excluding Mississippi, which only authorizes aseptic concentrates, and California and Nevada, which solely authorize 64 ounce containers.

MANAGED BY DAIRY MANAGEMENT INC™

November 6, 2006

Ms. Patricia N. Daniels, Director Supplemental Food Programs Division Food and Nutrition Services U.S. Department of Agriculture 3101 Park Center Drive, Room 528 Alexandria, Virginia 22302

RE: Comments on WIC Food Packages Proposed Rule, Docket ID Number 0584-AD77

Dear Ms. Daniels:

The NATIONAL DAIRY COUNCIL® (NDC) submits the following comments on the docket referenced above. NDC appreciates the opportunity to submit comments on the U.S. Department of Agriculture Food and Nutrition Service's Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions to the WIC Food Packages Proposed Rule.

NDC is an organization that initiates and administers nutrition research, develops nutrition programs, and provides information on nutrition to health professionals and others concerned about good nutrition. NDC has been a leader in nutrition research and education since 1915. Through its affiliated Dairy Council units, NDC is recognized throughout the nation as a leader in nutrition research and education.

The USDA's proposed rule has been more than 10 years in the making, and is based on recommendations from the 2005 National Academy of Sciences' Institute of Medicine IOM) report, "WIC Food Packages: Time for a Change." USDA noted that the IOM report indicates fundamental changes have occurred over the last 30 years in the health and nutrition risks faced by the WIC population. IOM reports that diets have improved with respect to several nutrients that were deemed deficient when the WIC program began – protein, calcium, and vitamins A and C are cited – and that overweight and obesity are bigger problems today than they were when the program was established. Changes in the ethnic and cultural demographics of the WIC population as well as new developments in nutrition science knowledge also contributed to the decision to revise the packages.

The IOM committee and USDA have proposed the addition of fruits, vegetables and whole grains to be more consistent with the 2005 Dietary Guidelines and support the needs of the current WIC population. The proposed rule, which departed from the IOM recommendations in two significant areas -- a \$2 reduction in the fruit and vegetable voucher and the exclusion of yogurt as a substitute for fluid milk -- include multiple changes to the WIC packages without increasing the cost of the WIC program. Accomplishing multiple and sometimes conflicting goals was undoubtedly a challenging exercise.

A brief summary of NDC's comments is included immediately below; a full explanation follows this summary.

Summary of Comments

There is sound science to support the alignment of the WIC dairy group allowances with the 2005 Dietary Guidelines for Americans and My Pyramid, by allowing adequate milk, cheese and yogurt to provide flexibility and variety for individuals to meet nutrition needs and cultural preferences. The need for cost neutrality has allowed the addition of some foods, but also limited other nutrient-rich options. Nutrition science supports the following adjustments to the proposed rule to ensure consistency with the DGA, provide culturally appropriate choices, support nutritional equivalent choices for those who do not drink milk, and provide key nutrients important in the diet of WIC participants:

Increase allowance for cheese substitution as an excellent source of calcium: Cheese is an excellent source of calcium and a good source of protein, a popular food that fits into a variety of food patterns, and is often well-tolerated by people who have trouble digesting lactose. Allowing even 2 to 3 pounds of cheese per month would offer significant nutritional benefits to program participants.

Allow partial substitution of yogurt for milk as recommended by IOM: Yogurt is an excellent source of calcium and protein, a good source of potassium and some yogurt contains vitamin D. Yogurt is well-tolerated by those who are sensitive to lactose and fits into a variety of food patterns.

Make reduced-lactose and lactose-free milk the preferred substitutes for fluid milk for those with lactose maldigestion: The DGA says that "the most reliable and easiest way" to deal with lactose maldigestion is "to choose alternatives within the milk food group." Clearly identifying reduced-lactose or lactose-free milk as a substitute and eliminating current requirements to obtain reduced-lactose or lactose-free milk would help ensure WIC participants can follow the DGA and get the nutrients they need.

Provide all women 3 servings of milk: Women who choose not to breastfeed would enhance their nutrition by meeting the DGA recommendations for milk. Not only is it important for the health of the mother, but children will more likely consume milk if their mothers do so.

Culturally Appropriate Foods: It is unclear which WIC participants will benefit from the addition of soy beverage and tofu to cheese as allowed milk substitutions, and whether the choice to include tofu but not yogurt as a milk substitute as recommended by the IOM committee will be acceptable among the primary cultural groups in WIC. Cost constraints led to the limits on milk substitutions from the dairy group of only one pound of cheese/month; including adequate milk, cheese and yogurt in the revised packages will meet the USDA's goal of providing culturally appropriate foods for the WIC population.

Program Implementation: Given the size of the WIC program, the scope of the proposed changes, and the wide diversity in the WIC population, program goals would be well-served if the new packages were tested to determine whether expected outcomes such as nutritional improvements, cost neutrality, package acceptability, cultural appropriateness of additions and substitutions, and efficacy of incentives occurred. Testing major proposed changes via partial implementation before instituting nation-wide would strengthen the final packages.

Comments

1. Milk Allowance in the Proposed Rule

The IOM committee identified key priority nutrients that the report found to be low in WIC participants' diets and those that were found to be in excess:

- Breastfed infants 6-11 months: Intakes are low in zinc and iron.
- Children 1-4 years old: Intakes are low in vitamin E, fiber, potassium and iron. Those deemed in excess of requirements include zinc, pre-formed vitamin A, sodium, calories and saturated fat.
- Pregnant, lactating, and non-breastfeeding women: Intakes are low in are calcium, iron, magnesium, vitamin E, potassium and fiber. Nutrients with moderate levels of inadequacy are vitamins A, C, B6 and folate. Those deemed in excess include saturated fat and sodium as a percentage of calories.

Milk is a nutrient-dense beverage that has been a core component of the WIC food packages since the program began. Milk contains nine essential nutrients, including calcium, phosphorus, potassium, protein and vitamins A, D, B12, riboflavin, and niacin. Included among these are three key nutrients identified by the IOM as lacking in the diets of WIC-eligible women -- calcium, potassium and magnesium. Dairy nutrients are also critical to the healthy growth and development of nutritionally at-risk children. Milk and milk products are a core component of a healthful diet for all Americans, according to the 2005 Dietary Guidelines for Americans² (DGA) and MyPyramid. The DGA recommends 3 cups of low-fat or fat-free milk or equivalent milk products for all Americans 9 years and older and for children 2-8 years old, 2 cups of low-fat or fat-free milk or the equivalent. On average, most Americans do not meet these recommendations. NOTE: See Appendices for a summary of the health benefits of

adequate dairy consumption including its role in bone health and healthy blood pressure among others, and an article that outlines estimated cost savings to healthcare associated with adequate dairy consumption.⁴

The proposed rule recommends reductions in the milk allowances in the current package from approximately 3-4 cups of milk to age-appropriate DGA recommended serving levels for children of approximately 2 cups/day and for most women of 3 cups/day, except for postpartum non-breastfeeding women, whose milk allowance would be reduced to a maximum of about 2 cups/day. These changes were made to accommodate the addition of foods such as fruits, vegetables, whole grains and tofu.

In addition to the nutrient package delivered by milk and other dairy foods, they are safe, reasonably-priced, readily available products that are processed and distributed within a well-established market network. These characteristics of dairy foods assure program administrators and participants that fresh dairy foods will be available in essentially all locations and areas of the country, they will deliver a known amount of nutrients, and can be used easily by participants. Consistent products ease the administrative burden at the state level and the shopping process at the individual level. Products that attempt to imitate dairy do not have standards of identity, and their processing methods and nutrient contents can vary widely.

The DGA identifies milk and milk products as especially important in the diets of children and adolescents, as a major source of dietary calcium and other nutrients, such as potassium and magnesium, critical to bone health. USDA has appropriately extended this emphasis into the proposed rule: Milk is recognized as the preferred source for bone-building nutrients for children, and the proposed rule allows soy beverages as a milk substitution **only** when children cannot drink milk due to a medical condition. The USDA states in the proposed rule:

"The 2005 Dietary Guidelines for Americans stresses the importance of milk consumption in the development of bone mass in children. While soy products may be an appropriate choice for children who cannot consume milk, the IOM does not believe that soy should be made available to satisfy participant preference in the absence of a medical need."

Two reports published in 2006 by the American Academy of Pediatrics (AAP), "Optimizing Bone Health and Calcium Intakes of Infants, Children, and Adolescents" and "Lactose Intolerance in Infants, Children and Adolescents," emphasize the importance of adequate dairy intake to meet calcium recommendations, including for children with lactose intolerance. AAP recommends 3-4 servings of low-fat milk, cheese or yogurt to help children and adolescents meet calcium requirements, and states that children with lactose intolerance should consume dairy foods to ensure key nutrient intakes. AAP recommends strategies for dairy consumption for children and adolescents with lactose intolerance to ensure adequate dairy food intake.

Although the USDA's proposed rule acknowledges the importance of milk for children's health, it treats milk and dairy foods differently in the food packages for women. In the proposed rule, soy beverage is fully substitutable for milk, whether due to a medical need such as lactose maldigestion or for cultural, religious or other reasons.

Other health professionals recommend regular consumption of dairy foods for health, including the Surgeon General's Report on Bone Health and Osteoporosis⁷ and the National Medical Association (NMA). The NMA is the nation's largest organization representing physicians of African descent in the United States and the Caribbean, and is recognized as the collective voice of more than 30,000 physicians and patients they serve. In their Consensus Report on The Role of Dairy and Dairy Nutrients in the Diet of African Americans, NMA recommends 3-4 daily servings of dairy foods for African Americans. The report points out that estimates of prevalence of lactose intolerance, such as values provided by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), are exaggerated because lactose intolerance diagnoses are often based on artificial dietary conditions, whereas the presence of symptoms in the real world depends on how much lactose is consumed in food. Dairy food intake among African Americans is lower than the general population, and though lactose intolerance has been cited as a reason for low intake among ethnic minorities, it is likely not the only reason for low intakes. Lactose intolerance has a physiological basis, but psychological and cultural factors may also sustain it.

The DGA recommends dairy foods as the first choice among those who choose not to drink milk:

"If a person wants to consider milk alternatives because of lactose intolerance, the most reliable and easiest ways to derive the health benefits associated with milk and milk product consumption is to choose alternatives within the milk food group, such as yogurt or lactose-free milk, or to consume the enzyme lactase prior to the consumption of milk products. For individuals who choose to or must avoid all milk products (e.g., individuals with lactose intolerance, vegans), non-dairy calciumcontaining alternatives may be selected to help meet calcium needs."

The proposed rule provides the DGA recommendations for dairy for almost all groups in WIC, and NDC recognizes the very difficult challenge faced by USDA in making decisions about meeting the nutritional needs of the WIC population without increasing overall costs. However, the proposed rule is inconsistent with the DGA recommendations for dairy food intake in several respects.

Like the DGA, the IOM recommended that the dairy group be represented by milk, cheese and yogurt, the main foods in the milk group in MyPyramid, in addition to milk substitutions of tofu and soy beverages to meet particular needs. By excluding yogurt as a milk substitution, by reducing cheese substitutions to one pound for all participants except breastfeeding women, by offering soy beverage as fully substitutable for milk while not mentioning the role of reduced-lactose milk for those with lactose maldigestion, and by providing tofu as a milk substitute, which likely provides a

culturally appropriate alternative to milk only for a small portion of the WIC population, the proposed rule may not fulfill key criteria IOM sought to follow as they revised the WIC packages.

These are Criterion 1: The package reduces the prevalence of inadequate and excessive nutrient intakes in participants, and Criterion 2: The package contributes to an overall dietary pattern that is consistent with the DGA, for individuals two years of age and older.

The proposed changes may in fact heighten concerns expressed by the IOM about calcium and vitamin D intakes, especially for women. To be consistent with the DGA would mean providing variety and flexibility within the dairy group, such as increasing the allowable substitution for cheese including reduced-fat options, and offering yogurt (preferably fortified with vitamin D) as an option.

Further, WIC nutrition education, if it is to thoroughly and accurately reflect official dietary guidance of the U.S. government, should include information about the health benefits associated with adequate consumption of dairy foods, risks to nutrient intake if milk substitutes are used (as recommended by the IOM committee), and the DGA recommendation to choose dairy (such as reduced-lactose milk, hard cheese or yogurt for those who have lactose maldigestion) first for reliable delivery of dairy nutrients.

Milk Key Points

- The IOM recommendation to reduce milk servings in the food package for children ages 1-5 was made despite the IOM noting a concern that intakes of milk and milk products are lower than recommended on average for children ages 2 through 4 and women in the childbearing years. Although IOM found that WIC pre-school children's' diets are no longer lacking in calcium and other WIC nutrients, there is a risk that proposed revisions may compromise that status.
- USDA states that reducing the "amount (emphasis added) of milk provided through WIC is consistent with recommended limits on saturated fat, total fat and cholesterol consumption put forth in the DGA 2005."

Reducing the allowable fat content in fluid milk, as in the proposed rule, will limit the consumption of saturated fat, total fat and cholesterol consumed via WIC-supplied foods. However, there is no assurance that reducing the amount of milk provided through WIC will have an effect on total fat or saturated fat consumption. Dietary choices made outside the WIC program may offset reductions in fat and/or saturated fat consumption achieved through WIC program changes.

Research by Dr. Adam Drewnowski indicates that economics is a major driver of obesity, and he has shown that less expensive foods tend to be higher in fat and sugar. ¹⁰ The net effect of reducing nutrient-rich foods like milk in the WIC package on fat and saturated fat intake is not known, and the reduction may have negative

consequences on nutrient intake, such as reductions in calcium, potassium and magnesium.

- For postpartum non-breastfeeding women, reducing the number of servings of milk from about 3 servings to 2 is not consistent with the DGA, which recommend 3 servings for all adults. While this proposal was designed as an incentive to encourage non-breastfeeding women to breastfeed, the reduction may make it more difficult for these women to obtain the dairy nutrients in which their diets are low. Mothers who choose not to breast feed would be penalized by receiving less food, potentially compromising their health. The health benefits of 3 servings of milk and milk products are well-documented, yet the efficacy of this food-based incentive has not been proven. Taking the health of the infant and the mother into account, nutrition science would support providing mothers who choose to or cannot breast feed with the same amount of milk 3 servings as those who choose to breast feed.
- The IOM report states that the highest priority nutrients to increase in the diets of women of reproductive age include calcium, magnesium, and potassium. Other priority nutrients targeted for increased intake include vitamin A and vitamin D. Milk provides all of these nutrients consistently, affordably and it is widely available. However, the proposed rule decreases milk servings for women and limits dairy group substitutions.

According to the 2005 Dietary Guidelines Advisory Committee (DGAC) report, milk is a major contributor¹¹ of riboflavin, vitamin B12, calcium and phosphorus, and a substantial contributor¹² of vitamin A, thiamin, vitamin B6, magnesium, zinc, potassium, carbohydrate, and protein. Milk is the main food source of potassium in the diet.¹³

Because cereal and milk are often eaten together, it is not known how the reduction
in the allowance for milk and the change in the definition for allowable whole grain
cereals may affect the consumption of these foods. Both foods provide key nutrients
to WIC participants, and changes to both allowances raises concern about the
possible affect on nutrient intake.

2. Variety and Flexibility

The 2005 DGA recommends all Americans "consume a variety of nutrient-dense foods and beverages within and among the basic food groups" as a key recommendation to ensure consumption of the foods and nutrients needed for a complete, balanced diet. The IOM committee recognized that variety within food groups will encourage intake of nutrient-dense foods and minimize monotony when it states in Chapter 4:

"Among the features that may improve the incentive value of the WIC food packages and encourage participants to consume the foods provided are:

- A wider variety of foods; and
- More participant choices"

The IOM committee also states the following on the topic of flexibility and variety:

"The committee urges the FNS to retain, and possibly expand, the flexibility proposed for the revised food packages, so as to allow state and local agencies to adapt the packages to the needs of their WIC populations. It further recommends that WIC state agencies aim for the maximum variety and participant choice in food selections consistent with foods available in their area and with cost containment."

The goal of increasing variety and flexibility led to the IOM recommendations for new foods in the WIC package, such as whole grains, soy beverage, tofu and yogurt, and additional fruits and vegetables. It is worth examining whether goals for variety and flexibility have been met when it comes to alternatives offered within the dairy group, and to meeting the cultural preferences of the majority of WIC participants.

The DGA recommendation for 3 servings of dairy foods is for milk, yogurt and cheese. The USDA chose to exclude the IOM recommendation for yogurt, and it allows cheese to be substituted for milk at no more than one pound/month. Offering previously unavailable foods such as tofu may be welcome to some; however, it does not address the needs of people in the program who do not currently, or do not wish to start to, consume tofu and would prefer cheese or yogurt. Flexibility in the types and amounts of dairy foods is warranted to accommodate cultural consumption patterns among these participants and to be consistent with the DGA and MyPyramid. It is not known how the limited availability of dairy-based milk alternatives – one pound of cheese/month – may affect nutrient intakes (especially calcium) and incentive values of the package.

Through the foods offered in the WIC package and nutrition education, one goal of the WIC program is to have contact with children at ages at which they are developing important lifelong nutrition habits. Nutrition guidance recommends consuming a variety of foods from each basic food group, such as a variety of colorful fruits and vegetables, or milk, cheese and yogurt within the dairy group, to consume adequate nutrients. One of the reasons put forth by the National WIC Association to revise the food packages was to improve the opportunities to conduct nutrition education by having the package better reflect the DGA. The IOM report states that by being more consistent with the DGA and with current dietary recommendations for infants and young children, the packages hold more potential for effective nutrition education. Offering milk, cheese and yogurt would be consistent with current DGA and IOM recommendations.

Offering a variety of dairy foods can help individuals meet dairy food recommendations by providing the healthy foods they consume regularly. NDC recently conducted an analysis of data from women and children in NHANES 1999-2002 who have a Poverty Income Ratio less than or equal to 1.85. Forty-seven percent of the children 1-5 years old met dairy recommendations, while only about 10 percent of women aged 15-40 met recommendations. For children, 92 percent drank milk, 68 percent ate cheese and 6 percent ate yogurt. For women, 76 percent consumed milk, 66 percent consumed cheese and 3 percent consumed yogurt. Among women, those that consumed yogurt or cheese

obtained almost one more dairy serving per day (0.91 and 0.96 servings/day, respectively) compared to those who did not consume those foods. Among children, those who consumed yogurt obtained almost one more dairy serving per day (0.88 serving/day), while those who consumed cheese obtained about half a serving more per day (0.56 serving/day) compared to those who did not consume those foods.

3. Substitutions Allowed for Milk in the Proposed Rule

A. Cheese

The proposed rule allows cheese to be substituted for milk at the same rate as in current packages, but the amount of the allowed substitution would be sharply reduced. For all groups except breastfeeding mothers, no more than one pound of cheese per month would be allowable for substitution; breastfeeding women could receive up to 2 pounds of cheese. While the proposed rule would reduce the overall milk allowance by 30 percent for children and for most women by 25 percent, cheese substitution would be reduced by 75 percent.

Cheese Key Points:

• In reducing the amount of allowable cheese substitution, USDA points to the DGA and notes, "(R)educing the amount of cheese that may be substituted for milk will reduce the saturated fat and total fat intake..."

As noted above with respect to the proposed reductions in fluid milk, USDA does not know how much dietary fat will be contributed by foods outside of WIC. Therefore, it is not known how the proposed WIC changes will affect total fat or saturated fat intake. Research by Dr. Adam Drewnowski indicates that economics is a major driver of obesity, and he has shown that less expensive foods tend to be higher in fat and sugar. The net effect of reducing nutrient-rich foods like milk in the WIC package on fat and saturated fat intake is not known, and the reduction may have negative consequences on nutrient intake, such as reductions in calcium, potassium and magnesium.

• Based on an analysis by NDC of women and children at a Poverty Income Ratio less than or equal to 1.85 in NHANES 1999-2002, 13 among children 1 through 4 years old, 92 percent drink milk, 68 percent eat cheese and 6 percent eat yogurt and among women 15-40 years, 76 percent consume milk, 66 percent consume cheese and 3 percent consume yogurt. Among women, those that consumed yogurt or cheese obtained almost one more dairy serving per day (0.91 and 0.96 servings/day, respectively) compared to those who did not consume those foods. Among children, those who consumed yogurt obtained almost one more dairy serving per day (0.88 serving/day), while those who consumed cheese obtained about half a serving more per day (0.56 serving/day) compared to those who did not consume those foods.

- According to the USDA, current mean monthly consumption of cheese among children is 1.57 pounds and among women 1.84 pounds in package V, 1.65 pounds in package VI and 2.65 pounds in package VII. As this is an average, it is clear that not everyone chooses this amount of cheese -- some individuals choose more and some choose less. Reducing substitutability to 1 pound/month for all participants would limit access to those who rely on cheese, and provide WIC participants with one serving of natural cheese (1½ ounce) for only about 10 days per month. Cheese (especially hard cheese such as Cheddar) is a low-lactose food, and is easy to tolerate for lactose maldigesters. It is popular across the majority of cultural groups served by the WIC program^{7,15} and can provide key nutrients for those who choose not to drink milk. An allowable substitution of 2-3 pounds of cheese including reduced-fat varieties would offer more choice within the dairy group, flexibility for WIC participants and serve well the dietary and cultural needs of WIC recipients. If the allowable amount was increased, it would provide more flexibility at the state level to include cheese in WIC packages according to individual needs and preferences.
- There are a variety of reduced-fat cheeses and cheeses made with part skim milk such as low-moisture, part skim Mozzarella available on the market. In addition to increasing the allowable substitution of cheese for milk, USDA could allow WIC recipients to substitute a mix of regular and reduced-fat cheeses, thereby providing choice to participants and market incentives to encourage the production of more reduced-fat cheeses. NDC notes that although the DGA recommends low-fat and fatfree milk, cheese and yogurt, there are limited low-fat and fat-free cheese options on the market. There are no fat-free natural cheeses available, though fat-free and low-fat process cheeses are. There are no low-fat natural cheeses available that fill the FDA definition for low-fat. Reduced-fat process cheese singles made with 2 percent milk are readily available, and there are a limited number of reduced-fat natural cheeses on the market. Part-skim mozzarella is readily available.

B. Yogurt

The USDA proposed rule departs from the IOM recommendations in two significant areas. One is a \$2 reduction in the fruit and vegetable voucher; the other is the exclusion of yogurt as a substitute for fluid milk. Both departures from the IOM recommendations were made to reduce the cost of the proposed rule, according to USDA.

In explaining its decision about yogurt, the USDA states that the price of yogurt, compared to the price of milk, would "considerably increase the monthly cost of the food packages for children and women." The department notes that soy beverage and tofu also have higher costs than milk. But, USDA argues, the amount of tofu that is likely to be selected by WIC participants is substantially lower than the amount of yogurt they would likely select. USDA estimates that about 10 percent of participants would choose soy beverage.

In an attempt to explain why soy beverage is allowed but yogurt is not, USDA writes that "(S)oy beverage can serve as an alternative for all or part of the fluid milk for adult

women, making it a more cost-effective substitute." As soy beverage is more expensive than fluid milk, and would be fully substitutable up to the maximum milk allowance, it is not clear what is meant by this statement.

Yogurt Key Points:

- Yogurt is an appealing, highly nutritious food enjoyed by women and children, that is often well-tolerated by those who have trouble digesting lactose. Yogurt is consumed regularly by fewer consumers than milk or cheese, but it can contribute key nutrients for those who choose not to drink milk. Providing yogurt as a substitute for milk, especially if yogurt was fortified with vitamin D, would increase WIC participants' access to a nutrient dense food that contains calcium, potassium, and vitamin D, nutrients that are low in the diets of women and/or children.
- Based on an analysis by NDC of women and children at a Poverty Income Ratio less than or equal to 1.85 in NHANES 1999-2002¹³, among children 1 through 4 years old, 92 percent drink milk, 68 percent eat cheese and 6 percent eat yogurt and among women 15-40 years, 76 percent consume milk, 66 percent consume cheese and 3 percent consume yogurt. Among women, those that consumed yogurt or cheese obtained almost one more dairy serving per day (0.91 and 0.96 servings/day, respectively) compared to those who did not consume those foods. Among children, those who consumed yogurt obtained almost one more dairy serving per day (0.88 serving/day), while those who consumed cheese obtained about half a serving more per day (0.56 serving/day) compared to those who did not consume those foods.
- One of the reasons the IOM recommended inclusion of yogurt as a substitute for milk
 was its acceptability across cultural populations served by the WIC program.
 Addressing the food preferences of various cultures was also the reason IOM
 recommended inclusion of soy beverages and tofu as substitutes for milk. From a
 cultural or nutritional viewpoint, the choice to include one substitute (soy) but not the
 other (yogurt), limits the potential success of WIC's objectives.
- The IOM analysis showed that the revised WIC package resulted in decreased intakes of calcium and vitamin D for pregnant, partially- or non-breastfeeding women; only breastfeeding women had increases in calcium and vitamin D with the revised package. The revised package also resulted in increases in potassium and magnesium for all women, while children showed a decrease in potassium. This analysis was done including yogurt as an option for partial substitution for milk. Yogurt is an excellent source of calcium and a good source of potassium, and if fortified, contains vitamin D. Some of the improvements estimated by the IOM may no longer be valid, while some of the estimated shortfalls may be more severe than the IOM estimated.
- When considering the nutrient needs of the WIC population, it appears that the
 decision about including yogurt was made based mainly on cost. USDA's rationale
 for the decision was not explained well in the proposed rule, and leads to questions
 about whether USDA adequately estimated how many people will be affected by the

choice to include to fu but not yogurt, and whether food preferences and cost differences were understood adequately to implement this change nation-wide. It is difficult to understand, on the basis of science, why USDA would be forced to include a nutritionally non-equivalent product as a substitute for milk due to cost constraints, but would not allow substitution of yogurt for milk. The needs of WIC participants may be better served by ensuring that the decisions about substitutions have the intended results of improving the WIC population's food and nutrient intake before full implementation occurs.

C. Culturally Acceptable Foods and Soy Products

In the packages for women, soy beverages would be substituted for milk at the rate of one quart of soy beverage for one quart of milk, up to the maximum amount of milk allowed in each food package. The proposed rule would permit calcium-set tofu to be substituted for milk at the rate of one pound of tofu for one quart of milk. For most women and children with a medical need, a combination of tofu and cheese could be substituted for up to four quarts of milk. Breastfeeding women have the option to substitute up to six quarts of milk for cheese and/or tofu.

Throughout the proposed rule, USDA cites the IOM report's recommendation to take into account cultural food preferences as part of the rationale for changes in the food packages. Clearly, this is a valuable approach for reaching WIC participants; they are more likely to meet their nutrition and education needs if they receive the nutrient rich foods they need in a familiar form that they will consume.

In discussing the addition of soy beverage and tofu as substitutes for milk, USDA says, "(T)hese products are culturally preferable to milk within some groups, and may be consumed by individuals with lactose maldigestion." The proposal does not provide any information on the cultural identity of these groups. Elsewhere, USDA notes a 16 percent decline from 1992 to 2004 in the percentage of WIC participants identified as white or black, accompanied by an offsetting 16 percent increase in the percentage of participants identified as Hispanic.

The proposed rule states: "A high prevalence of lactose maldigestion and low cultural acceptability have been widely cited as reasons for the low consumption of dairy products among people of color; Asian and African American women of child-bearing age are particularly at risk for low intakes of dietary calcium. Milk and cheese are not a part of traditional food patterns of many cultural groups."

Yogurt and cheese are culturally preferable to milk for some ethnic and cultural groups, and may be consumed by individuals with lactose maldigestion. Both Hispanic and African American populations regularly consume cheese as part of their diets^{7,15} and thus these foods contribute key nutrients to their diets. The proposed rule does not appear to take these "cultural preferences" into account. The reduced substitutability of cheese for milk in the proposed rule may hit hardest at Hispanics, who at 39 percent of all participants are the fastest growing population in the WIC program. For example,

Hispanic children consume milk at slightly below average levels in the US, but they are close to average consumers of cheese and yogurt.⁷ By contrast, Asian or Pacific Islanders represented 2 percent of the WIC population in 1992 and in 2004 represented just 3 percent.

NDC recognizes that balancing cultural preferences within nutrition and cost constraints is difficult and applauds the USDA's flexibility in responding to the needs of members of the WIC population. However, some of the changes may have a negative nutrition impact on the key parts of the WIC population, such as African Americans and Hispanics. Though lactose intolerance has been cited as a reason for low intake among some ethnic groups, evidence suggests that actual incidence of lactose intolerance has been exaggerated. In addition, cheese and yogurt – part of the dairy group as described by the USDA – are both well-tolerated by those with lactose intolerance, and are regularly consumed by African Americans, Hispanics, Caucasians and Asians.

The recently published report from AAP, "Lactose Intolerance in Infants, Children and Adolescents," emphasizes the importance of dairy foods in children's' diets, including for those who have difficulty digesting lactose. Children who have trouble digesting lactose can often manage their intolerance by using simple strategies such as drinking milk in smaller amounts with meals, substituting lactose free milk, choosing cheese, which is low in lactose, or choosing yogurt, which is easier to tolerate than milk for some. With these strategies, children can maintain key dairy nutrient intakes.

Culturally Acceptable Foods and Soy Products Key Points:

- For large groups within WIC, both cheese and yogurt are culturally acceptable milk alternatives that are well-tolerated by those who are sensitive to lactose. Inclusion of a variety of dairy foods in the diets of those who are sensitive to lactose is recommended by both the DGA and AAP. The goal of accommodating cultural needs and preferences in the WIC population could be accomplished by offering yogurt and more cheese as substitutions for milk, and clarifying the role of reduced-lactose milk in the food packages.
- Given the potential nutritional benefits of offering yogurt, the cost implications of offering yogurt in addition to soy beverage and tofu should be carefully considered by the USDA to ensure that foods that will provide variety and flexibility are included in the WIC package. In explaining the decision to not include yogurt, USDA assumed that 10 percent of participants would choose soy beverages, and assumed that African Americans, Asians and those WIC participants who do not choose milk or cheese will likely consume soy beverage. Consumption patterns vary within and between the ethnic and cultural groups in WIC; confirmation through measurement that these assumptions are sound, such as in regional comparisons as described earlier, would support effective implementation.
- NDC looked at dairy food consumption data from NPD's National Eating Trends® Service (NET).¹⁵ which monitors the eating and drinking habits of thousands of

individuals per year in two thousand households. This data represents the average intake over a five year period ending February 2006.

Among Caucasian, African American, Hispanic and Asian children aged 1-4 years, Caucasian children consume the most dairy foods (milk, cheese and yogurt) per capita while their African American counterparts consume the least dairy foods. African American children consume cheese at 20 percent below the average rate, milk at 40 percent below the average rate, and yogurt at 70 percent below the average rate. Hispanic children consume milk about 20 percent below the average rate, but are average consumers of cheese and yogurt. Asian children consume yogurt at above average rates, milk at average rates, and cheese below average. These data indicate that yogurt as an option would fit dietary habits of Asian American and Hispanic children, and provide an opportunity to educate African American children about yogurt as dairy option. However, under the proposed rule, these potential benefits will not be realized. Women from all groups fall within the average range of dairy intake, however we know from NHANES and CSFII that average dairy intake is low in women.

 Under the proposed rule, soy beverages (and calcium-set tofu) would be allowed as milk substitutes for children, but only when a medical condition such as lactose maldigestion, milk allergy, etc. is established. On this provision, USDA's proposed rule states:

"The 2005 Dietary Guidelines for Americans stresses the importance of milk consumption in the development of bone mass in children. While soy products may be an appropriate choice for children who cannot consume milk, the IOM does not believe that soy should be made available to satisfy participant preference in the absence of a medical need."

USDA's approach regarding soy as a milk substitute is different for WIC women and children. For children, the approach is nutrition-based, i.e. the decision to provide milk but not soy beverage to children without a medical need is based on the key nutrients milk provides. This approach solidly reflects the DGA. However, in the food packages for women, availability of milk and soy beverage is equivalent which does not reflect the DGA recommendation for the dairy group. Milk, cheese and yogurt are nutritionally important for adults as well as children, as demonstrated by DGA recommendations for 3 daily servings of low-fat or fat-free dairy foods for all adults. Dairy nutrient intakes of adults in WIC are more likely to be deficient than children. Some participants may prefer soy beverage, but by providing full substitutability of soy beverage to all women, a message is being conveyed that soy beverage is the nutritional equivalent to milk, which it is not.

 For those with lactose maldigestion who do not drink milk, the DGA recommends dairy foods, such as hard cheese, yogurt or lactose-reduced/free milk, as the first choice alternative: "If a person wants to consider milk alternatives because of lactose intolerance, the most reliable and easiest ways to derive the health benefits associated with milk and milk product consumption is to choose alternatives within the milk food group, such as yogurt or lactose-free milk, or to consume the enzyme lactase prior to the consumption of milk products. For individuals who choose to or must avoid all milk products (e.g., individuals with lactose intolerance, vegans), non-dairy calcium-containing alternatives may be selected to help meet calcium needs."

- The IOM committee recommended in Chapter 4 of their report that yogurt, calciumset tofu and soy beverage be offered as additional substitutions for milk for 1) people with a medical reason that limits milk consumption and 2) for those who avoid milk for cultural, religious, or other reasons. For those with lactose intolerance, the proposed rule is not clear about how reduced-lactose milk fits into the regulations. Currently, WIC participants must declare themselves lactose intolerant or have documentation from a doctor to receive reduced-lactose milk. Reduced-lactose milk should be as equally available as regular milk, and the first alternative for those with lactose maldigestion, followed by soy beverage. The role of reduced-lactose milk should be clarified in the proposed rule, and to be consistent with the DGA, dairy foods should be characterized through WIC education as the first choice, nutritionally, for those with lactose maldigestion.
- Based on preference, the addition of soy beverage may not provide a realistic, culturally appropriate alternative for many WIC participants. African Americans consume more yogurt than soy beverage. Per capita beverage intake data based on "eating occasions" from a nationally representative panel shows that soy beverage intake is low compared to milk intake among the main ethnic groups represented in WIC: African Americans, Hispanics and Whites (see table below).

Share of Intake Pane TNS NFO eSIP data						
Categories	Categories Ethnicity					
	Total	White	African American	Hispanic	Other	Choose not to answer
Total Beverages	477.9	494.6	429.2	445.3	402.1	448.5
Total Beverages-No Tap/Water	348.1	360.2	316.9	337.8	272.8	307.8
Total Milk	36.9	39.1	24.8	37.5	34.9	28.1
Total Soy Beverages	0.8	0.6	0.9	0.9	2.0	2.9

NDC also conducted a taste test among children and adolescents aged 8-16 years old that suggests a cultural preference for reduced-lactose milk over soy beverage for the main ethnic groups in WIC. Among African American, Hispanic and Caucasian children and adolescents, reduced-lactose milk was preferred over soy beverage; among Asian American children and adolescents, reduced-lactose milk was preferred but by a smaller margin. Although this is not, for the most part, the age range of the WIC population, it does suggest an ethnic or cultural preference for reduced-lactose milk.¹⁷

- Though tofu may fit naturally into some cultural or ethnic food patterns, it is not widely used by African American and Hispanic families. Therefore, it may not offer a realistic, culturally appropriate option to replace milk for these groups. Also, calcium-set tofu contains some of the micronutrients found in milk, but the nutrient content of tofu varies considerably among different calcium-set tofu preparations. Tofu may be more appropriate as a protein substitute than a milk substitute.
- Nutrition science supports USDA's recommendation of the requirement for a
 documented medical need in order for children to receive soy beverage as a substitute
 for milk. USDA is acting on the basis of good nutrition science in requiring the
 fortification of soy beverage with the nine essential nutrients found in milk, including
 8 grams protein/cup, to ensure key nutrient intake if a medical need such as lactose
 intolerance or milk allergy exists.
- USDA established fortification levels for select nutrients that must be added to soy beverage; however, USDA may not have considered the problem of calcium being contained in solids that settle to the bottom of soy beverage cartons.¹⁸ Soy beverage that contains settled solids could result in WIC participants consuming soy beverage that doesn't contain the expected level of calcium. When looking for a calcium-rich beverage, milk is among the most reliable choices.

The IOM committee recommended in Chapter 4 of their report that additional education be provided regarding nutrient shortfalls if milk alternatives are given to children, specifically, "through nutrition education parents or guardians will learn that children are at nutritional risk when milk is replaced by other foods." Because soy beverage is not nutritionally equivalent to milk, nutrition science supports these recommendations to be implemented as part of the proposed rule.

4. Program Implementation

WIC provides supplemental foods and nutrition education with the goal of improving nutrition status of the more than 8 million WIC participants. Given the size of the WIC program, the scope of the proposed changes, and the wide diversity in the WIC population, program outcomes would be well-served if careful consideration regarding implementation and evaluation of the changes were given to ensure that the changes instituted in the final rule have the intended consequences of improving nutrient intake. For example, although pre-school children in WIC have much improved intakes of the nutrients that the original WIC package was designed to address, it is not known whether the proposed package would compromise this significant accomplishment by its reductions in foods rich in some of these same nutrients. For women in WIC, who continue to have key nutrient shortfalls including calcium, potassium and magnesium, it is unclear what the ultimate effect of the packages will be on their nutrition status despite the IOM committee's rationale for the revisions.

The IOM committee recommended pilot testing or limited application of major package changes to examine the results of the proposed changes. The USDA has asked for input on a plan to phase in the most significant changes in the WIC packages, including the addition of soy beverage and tofu in addition to cheese as substitutions for milk. A pilot test was not included in USDA's plan to evaluate the results of these changes; a plan that allows for evaluation of the outcomes of the final rule, before nation-wide implementation, would better serve the WIC population by ensuring efficacy of the changes.

Implementation of the new WIC food packages provides an unprecedented opportunity to study a major public health initiative at its outset. An approach that allows comparison between participant groups who receive packages with or without key changes would provide valuable data about actual, rather than projected, usage and outcomes. The one-year implementation plan in the proposed rule would allow for smooth implementation of the new packages, but will not measure whether expected outcomes such as nutritional improvements, cost neutrality, package acceptability, cultural appropriateness of additions and substitutions, and efficacy of incentives occurred. The partial implementation plan described (implementing in 32 local sites, or 4 sites within up to 8 State agencies) for partially breastfeeding women, could be expanded so that such comparisons could be made. Because different regions of the country have different needs regarding ethnic and cultural preferences, testing in more than one geographic region would provide additional valuable information. Conducting research on actual WIC outcomes before nation-wide implementation provides opportunities for needed adjustments to maximize positive outcomes for the WIC population.

In closing, dairy foods have been part of the WIC program since it began due to the important nutrients it provides to women and children, and that continues in the proposed rule. NDC is looking forward to working with the USDA to continue to serve the more than 8 million at-risk women, infants and children in the WIC population with a food package that addresses their needs and improves their health.

Sincerely,

Jill Nicholls, PhD

Director

Nutrition & Scientific Affairs

Til Phane

National Dairy Council

Gregory D, Miller, PhD, MACN

Executive Vice President Science & Innovation

National Dairy Council

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Appendix I

Health Benefits of Dairy Foods National Dairy Council

Revisions to the WIC Food Packages Proposed Rule Docket ID Number 0584-AD77

Health Benefits of Dairy Foods and WIC

As of April, 2004, more than 8.5 million women, infants and children were enrolled in the WIC Program, an increase of 7 percent from the same time in 2002. The WIC program serves an estimated 54 percent of all U.S. infants and 25 percent of all U.S. children ages 1 year through 4 years, along with many of their mothers.

Dairy foods contribute more than 72 percent of the calcium in the nation's food supply.³ Milk is a good or excellent source of nine essential nutrients: calcium, vitamin D, protein, potassium, vitamin A, vitamin B12, riboflavin, niacin and phosphorous. A staggering 81 percent of the U.S. population is not meeting the 2005 U.S. Dietary Guidelines for Americans (DGA) recommended intake for dairy.⁴ Eighty-four percent of women between the ages of 20 and 50 years of age do not meet the DGA recommended intake for dairy.⁴ Though children on average consume close to recommended amounts (two servings), only about one-half of children ages 4-8 meet current recommendations for daily intake of dairy foods.⁴

According to the USDA, only slightly more than one-half of children aged 1 to 8 have adequate calcium intakes, and calcium intake declines dramatically with age. Women and adolescent girls have inadequate calcium intakes: only 9 percent of females 14 to 18 years old, 21 percent of 19-30 year old females, and 15 percent of 31-50 year old females meet calcium recommendations.

WIC participants are deficient in calcium as well.² While the mean calcium intakes of WIC infants and children exceed the Adequate Intake (AI), for women, mean calcium intakes are far below the AI in most cases. Women and girls between the ages of 14 and 44 who are pregnant or lactating consume on average about 75 to 95 percent of the AI for calcium. Women and girls between the ages of 14 and 44 who are nonbreastfeeding postpartum have a calcium intake of only 51 to 67 percent of the AI.² In addition to calcium dairy foods supply potassium, magnesium and vitamin A, which were identified as being low in the diets of WIC participants.² Calcium, potassium and magnesium were also identified in the Americans (DGA) as "nutrients of concern," low in both adults' and children's diets.⁶

The American Academy of Pediatrics recommends drinking three 8-ounce glasses of low-fat or fat-free milk per day (or the equivalent) to achieve the recommended adequate intake of calcium for children 4 to 8 years of age, and four 8-10-ounce glasses of milk per day (or the equivalent) for adolescents.⁷ The 2005 DGA recommends 3 cups/day of fat-free or low-fat milk or equivalent milk products (e.g., cheese, yogurt) as part of a healthful diet for adults and for some young children who are physically active. ⁶ For sedentary children ages 2 through 8 years, the recommendation is 2 cups of fat-free or low-fat milk or equivalent products per day. ⁶ The recommendation for children was largely due to the effect of dairy foods on bone health

A large body of evidence indicates that adequate intake of dairy foods, with their broad complement of essential nutrients, is a critical factor in risk reduction for several chronic diseases and can contribute to reduced healthcare costs associated with several chronic

medical conditions. It has been estimated that if Americans simply increased their intake of dairy foods to the currently recommended 3 to 4 servings a day, an estimated savings in healthcare costs would be in excess of 200 billion dollars over five years.⁸

Bone Health

Osteoporosis, which is characterized by low bone mass and bone tissue deterioration, leading to skeletal fragility, is now recognized as a "pediatric disease with geriatric consequences." According to the National Osteoporosis Foundation, 10 million Americans are estimated to have osteoporosis, and 34 million are at increased risk for the disease due to low bone mass, making it a major public health threat to 44 million Americans. Inadequate calcium and dairy food intake in youth set the stage for skeletal fragility in later life, resulting in a higher risk for osteoporosis and osteoporotic fractures, which can be debilitating and life-threatening. ¹⁰

Life Stage Calcium and Dairy Intake. Dietary calcium has been unequivocally demonstrated to enhance bone health at every stage of life, with high habitual intakes being associated with formation of greater bone mass in childhood and adolescence and with reduced bone loss and fracture risk in the elderly. In addition to being an excellent source of calcium, milk provides several nutrients essential for bone growth and maintenance, including phosphorus, protein, magnesium, potassium and vitamin D.

In an analysis of papers published between 1975 and 2000 on the relationship between calcium intake and bone health, Heaney found that of 52 investigator-controlled calcium intervention studies, 50 demonstrated better bone balance, greater bone gain during growth, reduced bone loss in the elderly or reduced fracture risk at high calcium intakes. Six of the intervention studies used dairy foods as calcium sources and all reported a positive link between dairy/calcium intake and bone health. All dairy interventions showed significantly positive effects that were as strong as, or stronger than, the effects of calcium supplements. Of the 86 observational studies, 64 showed a positive association between calcium and bone, confirming that the causal relationship observed in the intervention studies also exists in free-living populations.

Pregnancy. In pregnant women, sufficient maternal intake of calcium and other nutrients is necessary to support bone and teeth development in the infant. Teeth and bones begin to form during the first few months of pregnancy, and mineralization continues into adolescence. Several studies indicate that there is less fetal bone accretion among mothers who have low calcium intakes (<600 mg a day). A recent study from India of mothers and their children found that a higher frequency of intake of calcium-rich foods during pregnancy, including milk and milk products, resulted in greater bone density in their children six years postnatally. Maternal intake of vitamin D from milk is also important, as vitamin D deficiency during pregnancy is associated with disturbances in neonatal calcium homeostasis. 17,18,19

Childhood and Adolescence. Children require adequate calcium, vitamin D, protein and other dairy nutrients for proper bone growth, development and maintenance.^{7,11,20} The

teenage years are a period of rapid skeletal growth during which there is a critical "window of opportunity" to maximize peak bone mass and protect the skeleton against future risk of osteoporosis. ^{21,22,23} The low calcium intakes of children and adolescents is of great concern, because bone mass later in life is determined primarily by peak bone mass, which is 90 percent complete by 20 years of age.

The recent report from the American Academy of Pediatrics (AAP) Committee on Nutrition, "Optimizing Bone Health and Calcium Intakes of Infants, Children and Adolescents," states that it is important to help young children develop dietary practices that are associated with adequate calcium intake later in life. To accomplish this goal, AAP recommends that children get three servings of dairy products a day, including skim milk and low-fat yogurts, in order to meet calcium requirements. The 2005 Dietary Guidelines for Americans states that the consumption of milk products is especially important for children and adolescents who are building their peak bone mass and developing lifelong habits. ²⁴

Several studies in Chinese children in Asia have found that increasing milk intake during childhood and adolescence increases total bone mineral content, bone mineral density and indicators of bone strength. ^{25,26,27,28} Cheese can also improve bone mineral density. A recent study from Finland found that young girls experienced a greater increase in bone mass when consuming 1,000 milligrams of calcium from cheese than getting the same amount of calcium from a supplement, with or without added vitamin D. ²⁹ The reverse has also been found to be true: children who avoid milk have compromised bone health and are at greater risk for bone fractures. ^{30,31,32}

Adults. The 2004 Surgeon General's Report on Bone Health and Osteoporosis recognized that most Americans do not consume recommended levels of calcium and stated that three 8-ounce glasses of low-fat milk each day, combined with the calcium from the rest of a normal diet, would be enough to meet the recommended daily requirements for most individuals.¹¹

In adults, maintenance of bone health shifts to minimizing bone loss and preventing fractures. Several studies have reported significant fracture reduction with increased calcium intake. ^{12,33,34,35} Among RCTs, Chapuy et al. observed an approximately 40 percent reduction in hip and other extremity fractures within 18 months of employing a combination of calcium, phosphorus, and vitamin D. ³⁶ Dawson-Hughes et al. ³⁷ reported that supplementation with calcium and vitamin D reduced non-vertebral fractures by 55 percent within 3 years. In a review article about bone health in the elderly, total protein intake is also positively associated with increased bone mineral density, when calcium and vitamin D intake are adequate. ³⁸ Milk provides all three nutrients.

These studies also highlight the importance of the multiple nutrients contained in dairy foods. In an osteoporosis prevention study in which women received 1,000 mg/day calcium via either a supplement or milk, the latter group concurrently and significantly improved the intake of 11 other key dietary nutrients. Analysis by Barger-Lux and Heaney³⁹ of the diets of premenopausal women revealed that women consuming <60

percent of recommended levels of calcium also were consuming low levels of at least four other key nutrients (magnesium, riboflavin, thiamin and vitamin B12) that are delivered by dairy foods.

Vitamin D

Calcium and vitamin D work in concert to promote bone health, and milk is the main food source of vitamin D in the U.S. diet. Vitamin D is necessary for proper bone growth from infancy through puberty, and for bone maintenance in adulthood. Vitamin D increases intestinal absorption of calcium to help maintain calcium levels in the blood, and it stimulates bone cells that build the matrix of bone. With adequate calcium intake, but insufficient vitamin D, calcium uptake and utilization can be compromised, and bone matrix is not mineralized properly.

Vitamin D Deficiency. In children, a vitamin D deficiency leads to rickets, a disease which occurs before epiphyseal plates fuse, and in adults, to osteomalacia. Rickets, with typical bowing of the legs and slowed growth, was commonly seen in children in the U.S. up until the 1930's, when milk began to be routinely fortified with vitamin D. There are few dietary sources of vitamin D other than fortified milk. Recently, cases of rickets, or vitamin D deficiency, have made a comeback in the U.S., with some experts even deeming it an epidemic. 41,42

Vitamin D can be obtained through sunlight exposure, but increased use of sunscreens, limited time spent in outside activities, and reduced sun exposure – especially for those living in northern latitudes – can limit vitamin D production. Rickets and vitamin D insufficiency are attributed in part to low intake of vitamin D-fortified milk. The topic of vitamin D was reviewed at a recent NIH conference entitled "Vitamin D and Health in the 21st Century: Bone and Beyond." The conference highlighted the increased appearance of deficiencies, especially in dark-skinned populations, infants and pregnant women. The conference highlighted the increased appearance of deficiencies, especially in dark-skinned populations, infants and pregnant women.

Pregnant women with inadequate vitamin D status can give birth to infants with vitamin D deficiency and poor calcium status. In adults, frank vitamin D deficiency is rarely observed in the U.S., but marginal vitamin D deficiencies over many years can exacerbate the development of the long-latency bone disease osteoporosis⁴⁴ or osteomalacia. Subclinical vitamin D deficiency has also been identified in otherwise healthy adolescents. Some experts believe that higher vitamin D requirements are warranted in some populations, including pregnant women. Recent research also suggests that getting enough vitamin D may help protect against other chronic diseases such as diabetes, metabolic syndrome and breast cancer. Physiological syndrome and status of the syndrome and syndrome

Hypertension

Substantial scientific evidence indicates that calcium or calcium-rich dairy foods have a beneficial effect on blood pressure regulation. The DASH (Dietary Approaches to Stop Hypertension) study was the first study of its kind to examine the

effect of whole dietary patterns, rather than individual nutrients, on blood pressure.⁵³ The study found that a dietary pattern that including 8-10 servings of fruits and vegetables and 3 servings of low-fat dairy foods resulted in a significant reduction in blood pressure. A 1984 analysis of the first National Health and Nutrition Examination Survey (NHANES I), comprising dietary data from more than 10,000 American adults identified an inverse association between dietary calcium and blood pressure levels; dietary calcium intake >1000 mg was associated with a 40-50 percent reduction in hypertension prevalence.⁵⁸ Of the 17 nutrients assessed in that study, calcium and potassium were the two nutrients that differed significantly in intake between persons with and without hypertension. A dietary pattern low in calcium, potassium and magnesium has been associated with hypertension. Using data from NHANES III and NHANES IV, researchers demonstrated that this association has persisted over two decades.⁵⁹ The relationship between higher calcium intake and lower blood pressure has now been reported in numerous studies. 60,61,63,63,64 There is data demonstrating that it is not single dietary components, but the overall dietary pattern that has the greatest influence on blood pressure. A nutritionally complete diet rich in fruits, vegetables and low-fat dairy foods has been clearly proven to significantly lower blood pressure in all population groups. 65

Dairy vs. Supplements. RCTs that have assessed the effects of calcium or dairy products on blood pressure suggest a blood pressure-lowering effect of adequate calcium consumption from foods and supplements. ^{53,54,55,57} Although blood pressure responses to changes in nutrient intake typically vary among individuals, the beneficial blood pressure effect tends to be more consistent when foods rather than supplements are used as the calcium source. ^{53,54,58} This finding indicates that calcium may serve as a marker for dairy foods, and that observed blood pressure benefits are not derived solely from calcium, but from the full nutritional profile of dairy foods. Milk is also a good source of potassium, which helps maintain normal blood pressure. ⁶⁶ It has been suggested that milk proteins may be responsible, in part, for dairy's blood pressuring lowering effects. ^{67,68,69}

Children. According to the Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents, primary hypertension is now known to be a common occurrence in children. Low intake of dairy products may be a contributing factor to high blood pressure in childhood. In the first published study of the effects of dairy and fruits and vegetables on blood pressure changes among children, researchers analyzed 8 years of follow-up data from 95 children in the Framingham Children's study, and found that preschool-aged children who consistently consumed more dairy products (2 or more servings/day) had smaller yearly gains in systolic blood pressure throughout childhood compared to children consuming lower amounts. The greatest blood pressure benefit was seen with the combination of higher intakes of dairy and fruits and vegetables. The results were similar for the children during preschool years or during elementary school.

Adults. In the landmark controlled-feeding intervention trial Dietary Approaches to Stop Hypertension (DASH)⁵³ persons with high-normal blood pressure consumed one of three diets for 8 weeks. A control, or "typical American," diet was compared to a diet rich in fruits and vegetables (8-10 servings/day) and to a third diet containing fruits and

vegetables plus 3 servings of dairy products/day and was lower in total fat, saturated fat and high in fiber. The latter, the "DASH diet," resulted in significant reductions in both systolic and diastolic blood pressure compared to the typical American diet. The fruits-and-vegetables diet (without the dairy component) produced blood pressure reductions of roughly half that magnitude. The DASH diet with dairy foods resulted in significant decreases in blood pressure even among those with established hypertension. These blood pressure improvements rival those attainable with antihypertensive medications. ⁵³

In the Coronary Artery Risk Development in Young Adults (CARDIA) Trial, a multicenter population-based prospective observational study, a consistent reduction was observed in the incidence of hypertension with higher consumption of dairy foods. The odds of elevated blood pressure were lower by nearly 20 percent for each daily eating occasion of dairy products. A 2005 prospective study of men and women in Spain found that intake of low-fat dairy was associated with a lower risk of incident hypertension, even after controlling for several potential confounders such as age, sex, physical activity, body mass index (BMI) and other major dietary factors related to hypertension. The controlling for several potential confounders such as age, sex, physical activity, body mass index (BMI) and other major dietary factors related to hypertension.

African Americans. The prevalence of hypertension in blacks in the U.S. is among the highest in the world, affecting more than 40 percent of the African American population. Ta, Ta, Compared with whites, hypertension in African Americans also develops earlier in life and average blood pressures are much higher. African Americans have higher rates of death from stroke and heart disease, and a dramatically higher rate of hypertension-related renal disease than those in the general population. Researchers from the Bogalusa Heart Study found that African American children had significantly higher blood pressure than white children starting as early as age 10 years.

Subgroup analysis of the DASH trial revealed a significant blood pressure lowering effect of the DASH diet among African Americans. These reductions were approximately double those achieved with the fruits-and-vegetables diet without dairy foods. Particularly noteworthy in this cohort, in which lactose maldigestion is presumed to be common, was the lack of adverse gastrointestinal effects with the addition of 3 dairy servings to the daily diet. There were no dropouts of African American participants due to an inability to tolerate the diet.

It has been suggested that hypertension should be the "index disease" for determining calcium requirements for blacks, instead of bone density, as this population has higher bone density and lower calcium requirements for supporting bone. The National Medical Association (NMA), the organization that represents physicians of African descent, recommends three to four servings of low-fat dairy a day for African Americans to reduce the risk of chronic diseases.

Pregnancy. Calcium also provides benefits for pregnant women. Sufficient calcium during pregnancy helps prevent pregnancy-related hypertension or preeclampsia, a condition with potentially grave consequences for mother and fetus. ^{79,80} A study from the Netherlands found that while an increased milk intake was associated with a decreased

risk of developing preeclampsia during pregnancy, supplementation with calcium tablets was not. Supplementation with calcium can also improve blood pressure in offspring of supplemented women. In an extension of a study that examined the effect of calcium on preeclampsia, children born to women supplemented with 2 grams of calcium beginning between weeks 13 and 21 of gestation until delivery had systolic blood pressure that was significantly lower than the placebo group at three months and two years. Milk consumption in pregnant women is also associated with infant birth weight. Another study found that for each additional cup of milk consumed daily by pregnant women, birth weight increased by 41 grams; each additional microgram of vitamin D, of which milk is a major dietary source, was associated with an 11 gram increase in birthweight.

Lactose Intolerance

Lactose intolerance is characterized by a reduced ability to digest lactose, the main sugar in milk leading to unpleasant gastrointestinal symptoms. Gas-producing bacteria in the gut ferment the lactose, and may cause symptoms of bloating, flatulence, abdominal pain and diarrhea. Symptoms result when the amount of lactose consumed exceeds the body's ability to break it down into its constituent sugars, glucose and galactose. Whether an individual experiences symptoms depends on the level of lactase activity, the amount of lactose consumed, gastrointestinal transit and ability of the colon microflora to metabolize lactose. Despite the commonly held belief that African Americans, as an ethnic group, experience a high rate of lactose intolerance, recent research findings revealed that more than 75 percent of African Americans do not consider themselves to be lactose intolerant. African Americans who consume medium-to-high amounts of dairy foods per day (more than one serving) are less likely to experience symptoms.⁷³ Not all those with lactose maldigestion experience the symptoms associated with lactose intolerance.

Results of double-blind, randomized, crossover trials indicate that most individuals, including African-Americans, with primary lactase deficiency can tolerate one cup (240 ml) of milk with a meal or two cups (480 ml) if consumed in divided doses with breakfast and dinner. The same investigators found that women with lactase non-persistence can eat a dairy-rich diet that includes milk, yogurt and cheese, supplying about 1,500 mg of calcium per day, without impediment. A study with adolescent African-American girls, most of whom were lactose intolerant, found that adaptation to lactose occurred when they were given a dairy-rich diet for three weeks. Gastrointestinal symptoms were negligible.

Both the American Academy of Pediatrics Committee on Nutrition's report, "Lactose Intolerance in Infants, Children, and Adolescents," ⁸⁷ and the National Medical Association's "Consensus Report on The Role of Dairy in the Diets of African Americans" recognize that avoidance of dairy products in childhood may lead to inadequate calcium intake and consequent suboptimal bone mineralization. Avoiding milk also has a negative effect on vitamin D and protein intake, both important nutrients for growing children. ⁸⁷ To reduce symptoms associated with lactose intolerance, the following strategies can be effective: 1) Consume three to four servings of dairy a day 2)

Consume milk in small portions with food (about ¼ to ½ glass) 3) Consume hard cheeses, such as cheddar or Swiss 4) Consume live-culture yogurt and 5) Use digestive aids containing lactase before consuming dairy foods.^{73, 87}

Body Weight and Composition

The available data provide strong support for a beneficial effect of increased dairy foods on body weight and body composition. Animal studies have demonstrated an important role of increased dairy on decreasing body weight and body fat during over-consumption and during energy restriction. Several observational studies have indicated a statistically significant inverse relationship between dairy/calcium intake and body weight and fat. Furthermore, randomized clinical trials have demonstrated an effect of three servings per day of dairy products (milk, yogurt, cheese) on body weight and fat loss under caloric restriction in obese adults

Adults. Epidemiological data and randomized clinical trials indicate that diets including dairy products help individuals manage their body weight and fat. Specifically, randomized clinical trials have shown that three servings of dairy foods a day result in significant reductions in fat mass in obese adults in the absence of caloric restriction and accelerate weight and body fat loss when accompanied with caloric restriction. 88,89,90 In another study of obese subjects, isocaloric substitution of yogurt for other foods significantly augmented fat loss and reduced abdominal fat deposits during energy restriction. An inverse relationship was demonstrated between dairy consumption and BMI in a group of healthy men and women. In a study of African American adults, consuming three servings of dairy a day was found to result in a two-fold greater weight and fat loss compared to those consuming less than one serving of dairy a day under caloric restriction; without caloric restriction, including three servings of dairy foods compared to one serving resulted in a reduction in body and trunk fat and improved metabolic profiles.

Children. Overweight children are at increased risk of being overweight or obese as adults. Also, overweight increases risk of chronic disease during childhood as well as in adulthood. Although inconclusive, some evidence suggests that the increasing intake of high-sugar and nutrient-poor beverages relative to a decrease in milk intake may increase children's energy consumption, potentially increasing their risk for overweight. Sp,96,97,98 When following children from grades 3 to 8, Lytle found that the proportion of children consuming non-nutrient dense beverages daily almost tripled, while milk consumption decreased by 10 percent. This displacement of nutrient-rich beverages, as well as foods, with non-nutrient dense items may be influencing childhood obesity.

Compared to studies in adults, relatively little research has directly examined the relationship between calcium or dairy intake and body weight and fat in children and adolescents. In general, however, findings from epidemiological studies and randomized clinical trials designed to study bone health have shown either a beneficial or neutral relationship between calcium or dairy food intake and body weight and fat in

children. 95,103,104 The Framingham Children's Study found that children with low dairy intakes experienced greater body fat accretion throughout childhood into adolescence than those with greater intake of dairy. Similar findings from a cross sectional analysis were obtained from an Asian population of girls 9 to 14 years of age. The researchers concluded that decreasing soda and increasing dairy consumption may help maintain body fat and weight during adolescence. Moreover, intake of dairy foods has been shown to increase the nutritional quality of the diets of children and adolescents without adverse effects on body weight. 107,108,109,110,111

Additional Health Benefits of Dairy

Lead toxicity. Lead toxicity, from exposure to high levels of lead in the environment, is the number one environmental health threat to infants and children. Studies of calcium intakes and exposure to lead indicate that calcium intakes at or above recommended levels are associated with reductions in blood lead levels in women who are pregnant or lactating, especially in women who have a relatively high burden of lead. A significant inverse relationship has been observed between the blood lead levels of infants 6 months of age and their calcium intakes. In NHANES II (1976-1980), calcium intake was inversely associated with blood lead levels in children aged 1 to 11 years. The Centers for Disease Control and Prevention has stated that is important that a child with elevated blood levels of lead receive enough calcium.

Colon cancer. Colon cancer is the third most commonly diagnosed cancer in the U.S. 118 Clinical studies support a protective role for calcium or dairy foods against colon or colorectal cancer. 119,120,121 In addition, a recent case-control study in France found an inverse association between calcium, phosphorus, and dairy products and colorectal tumor risk. A meta-analysis of 10 prospective cohort studies found that high intakes of milk and calcium were associated with a reduced risk of colorectal cancer. A prospective study of more than 45,000 women found that increasing calcium intake from either diet or supplements was associated with reduced risk of colorectal cancer. Most recently, two new studies conducted in Sweden found a significant inverse relationship between both total calcium and dairy intakes and colorectal cancer. Dairy foods contributed most of the total calcium and milk was the single dairy food with the strongest influence on colon cancer risk. 125,126

An inverse relationship has been observed between consumption of dairy products and the odds of having acute coronary syndrome. Some studies have suggested that an increase in calcium and vitamin D from food and supplements may reduce the risk of type 2 diabetes and the metabolic syndrome. 128,129,130

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Appendix II

Estimated healthcare savings associated with adequate dairy food intake.

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Revisions to the WIC Food Packages Proposed Rule Docket ID Number 0584-AD77

Estimated Healthcare Savings Associated With Adequate Dairy Food Intake

David A. McCarron and Robert P. Heaney

Medical literature that has coalesced during the past two to three decades has identified adequate intake of nutrients from dairy foods as a common factor in the reduction of the disease burden of several common medical conditions. These include obesity, hypertension, type 2 diabetes, osteoporosis, kidney stones, certain outcomes of pregnancy, and some cancers. Treatment of these disorders, particularly cardiovascular, consumes a significant portion of the United States' healthcare budget. Drawing on accumulated data from prospective longitudinal studies and randomized controlled trials, this article summarizes the evidence of the net benefits of increased dairy food intake on these conditions, their outcomes, and their costs. Estimated im-

provements in outcomes were combined with available data on annual costs of the respective disorders. From the calculated annual impact, we generated first-year and fifth-year healthcare cost savings that would accrue if adult Americans simply increased their intake of dairy foods to the currently recommended 3 to 4 servings/d. Using conservative estimates of potential benefit, we project first-year savings of approximately \$26 billion and 5-year cumulative savings in excess of \$200 billion. Am J Hypertens 2004;17:88–97 © 2004 American Journal of Hypertension, Ltd.

Key Words: Healthcare costs, cost savings, economics, dairy foods, dietary calcium.

he escalation in society's health care costs has numerous causes. Contributing heavily to these are the increasing prevalence and management costs of several common medical conditions including cardiovascular disease and hypertension; obesity; type 2 diabetes; osteoporosis; breast, lung, colon and ovarian cancers; kidney stones; and adverse outcomes of pregnancy. In spite of dramatic advances in basic science and pharmacologic research, the aggregate costs of managing these disorders will continue to increase in the near term.

Although it is known that some of these conditions can cluster in a given patient, 1-4 and many are commonly preceded by poor diet and lack of physical activity, several misconceptions surround their management. Little credence is given to the likelihood that dietary modification will meaningfully influence the risk of developing one or more of these or its expression once present. Moreover, it is often assumed that healthcare savings from a public health nutritional strategy would not be realized until many years later. The most controversial point is whether current nutritional recommendations have focused on the appropriate issues, 5.6 a point that is particularly relevant given the dramatic increases in obesity and type 2 diabetes that have occurred in the face of—perhaps as a consequence of—existing strategies. The recent publication in

The New England Journal of Medicine of the first direct comparisons of low carbohydrate and low fat diets for weight and cardiovascular risk reduction^{7,8} illustrates how our nation's nutrition policy has gotten ahead of properly controlled clinical trials.

The assumptions that dietary changes would have little impact and produce only minimal immediate savings are likely incorrect. Data published in the past few years from randomized controlled trials (RCTs), limited intervention trials, and prospective studies of the relationship of diet to the expression of many chronic disorders suggest the opposite. Furthermore, recent findings have elucidated both the dietary components most critical to effecting desired outcomes and the best measures of the impact of dietary adjustments on various medical conditions. ^{1,9} It is now apparent that improvements in diet quality across the population could yield rapid and substantial healthcare cost savings. As this article demonstrates, adequate intake of dairy products is an integral component of improved diet quality and, thus, of subsequent cost savings.

We are well aware of the data that suggest higher dairy intake may contribute to various medical disorders, and address these in detail later in this article. From concerns about saturated fat and cardiovascular disease to assumed contributions to obesity and cancer, dairy foods have been

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From the Department of Nutrition (DAM), University of California, Davis, Davis, California and Osteoporosis Research Center (RPH), Creighton University, Omaha, Nebraska.

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Address correspondence and reprint requests to Dr. David A. Mc-Carron, Academic Network, 1221 SW Yamhill Street, Suite 303, Portland, OR 97205-2110, e-mail. dmccarron@academicnetwork.com

labeled by some as unhealthy. However, these concerns are typically supported by extrapolation and assumptions rather than outcome-driven evidence from carefully conducted laboratory or clinical studies. The apparent paradox regarding dairy foods and health was articulated recently in an article from the National Institute of Child Health and Human Development (NICHD) suggesting the time had come for large-scale human trials to assess the role of dairy intake on weight loss. ¹⁰ As those researchers did for obesity, we consider here the data regarding dairy product effects in several medical conditions and demonstrate that this food group makes strong, positive contributions to a healthy, high-quality diet in adults.

Two major studies, an RCT and a 10-year cohort study, have drawn attention recently to the benefits of a diet that includes adequate levels of dairy products. The Dietary Approaches to Stop Hypertension (DASH) trials9,11 and the Coronary Artery Risk Development in Young Adults (CARDIA) study¹ provide outcome data for hypertension control and metabolic syndrome incidence reduction. DASH examined dietary patterns rich in dairy products, fruits, vegetables, grains, and lean meat. CARDIA isolated dairy foods, but noted that as dairy intake increased, intake of fruits, vegetables, and grains also tended to rise. Moreover, the dietary pattern popularized as the DASH diet reflects the intake of these foods at the levels generally considered appropriate, 12 but rarely achieved by most Americans. The DASH diet is compatible not only with reductions in cardiovascular disease risk factors, 1,9,11 but also with the prevention and management of a number of other conditions that contribute substantially to escalating healthcare costs.

We assessed the available data for each of several medical conditions for which reasonable evidence exists that increased dairy product intake will lower the risk of its development or improve the treatment outcome. Although previous approaches have usually assessed single disease end points (eg, hypertension), this may not be the optimal approach. Even if effects are small for certain diseases, the aggregate of these effects will yield substantial cost savings for the total healthcare bill. Using published estimates of the costs of these conditions and estimates of risk reduction or improved outcomes, we generated a range of reductions in healthcare expenditures in the first and fifth years that would accrue if this dietary adjustment were implemented population-wide.

We have not undertaken a cost-benefit analysis properly considered. These have been done for calcium supplements in reference to osteoporosis, ¹³⁻¹⁶ and for this single end point, calcium alone has been found cost-effective. In her presentation at the 1994 National Institutes of Health (NIH) Consensus Conference, Chrischilles¹⁷ noted that calcium "is an example of a rare preventive intervention that actually may reduce net health care costs." It follows that the cost-benefit relationship improves when other conditions are added into the calculation, as the intervention remains the same while benefits expand.

It must be stressed that most of the disorders included

Table 1. Estimated annual healthcare costs

Disorder	Direct Costs (\$ billions)		
Obesity ¹⁹	\$ 61		
Hypertension ²⁰	. 34		
Stroke ²⁰	31		
Coronary artery disease ²⁰	58		
Type 2 diabetes ²¹	44		
Osteoporosis ²²	17		
Nephrolithiasis ²³	2		
Pregnancy outcomes ²⁴	12		
Colorectal cancer ^{25,26}	5		
Total	\$264		

here are multifactorial in etiology and pathogenesis. Insufficient intake of certain foods or nutrients is only a partial explanation for any of them, and full optimization of dietary intake cannot be expected to completely eradicate them. In estimating the health benefits of a dietary pattern, we recognize that it is not always possible to determine the specific contributions of single nutrients. What the data do reveal, however, is that dairy foods are important components of diets shown to be associated with improved health outcomes. 1,9,18 Evaluating associations between diet quality and all-cause, cardiovascular. and cancer mortality in >42,000 participants, Kant et al¹⁸ reported 30% to 40% lower risk of death in all three categories among women in the highest quartile of diet quality compared to those in the lowest. This finding alone makes this issue worth examining in more detail.

Estimated Healthcare Impact

We searched the medical literature for both RCTs and observational and prospective longitudinal studies that assessed 1) the relationship between dairy calcium or dairy product consumption and the prevalence of these disorders, or 2) the impact on the disorder of an intervention using calcium or dairy intake as a major component of the intervention. We distinguished between observational cross-sectional and prospective longitudinal studies because the latter in many cases were established to study specific conditions, whereas the former often include multivariate probing expeditions. Annual cost figures for the respective conditions (Table 1) were obtained from recent literature and published data from public and private health organizations. ^{19–26}

Table 2 lists the estimates of reduction in disease burden for each of the conditions whose risk of development or treatment outcomes have been linked to either dietary calcium or dairy product intake. For each of the clinical conditions, there are both randomized controlled trials and congruent observational data to support an estimate of clinical impact. For several end points, meta-analyses of observational studies or intervention studies are also available. 14,27–30

Table 2. Percent estimates of disease burden reduction with increased dairy product intake

Disorder	Randomized Controlled Trials	Cross-Sectional Observational Studies	Longitudinal Prospective Surveys
Obesity	50 ³⁶	85 ³⁴	301,40,81
Hypertension	70 ^{9,11}	35-45 ^{30,43,106}	65¹
Stroke	27 ⁹	50 ¹¹⁰	40 ¹⁸
Coronary artery disease	15 ⁹		30 ¹⁸
Type 2 diabetes	60 ^{45,46}		50¹
Osteoporosis	40-55 ⁵²⁻⁵⁵	25-55 ⁴⁸	25-55 ⁴⁸
Nephrolithiasis	51 ⁶⁶		50 ^{67,68}
Pregnancy outcomes	80 ^{27,35}	60 ^{69,70}	
Colorectal cancer	50 ^{73,74,78,79}	40 ⁷⁵	30 ⁷⁶

It should be noted that where calcium was identified in observational studies, its source was foods (mainly dairy), whereas many intervention trials used supplemental calcium. For several of the conditions addressed here, available data indicate that effects of supplemental calcium may be less than those of dietary calcium. ^{27,29,31,32} Lupton³³ has reviewed the mechanisms whereby dairy sources may be more effective in combating colon cancer promotion than are equivalent intakes of calcium carbonate. In estimating the point of maximal benefit, we calculated effects by assuming a population-wide increase in dietary calcium intake to the equivalent to 3 to 4 servings of dairy/d, or 1100 to 1400 mg of calcium/d.

To derive first-year cost savings for each condition, we used projections of benefit from clinical data that were midrange (Table 3). It was not possible to estimate year 1 cost reductions for all disorders; for stroke, coronary artery disease, and colorectal cancer, the published data do not indicate response times of less than several years.

Estimated Healthcare Savings

As shown in Table 2, the average benefit for all the conditions clusters around a 50% reduction in incidence risk or 50% improvement in the clinical condition. That

average benefit is exemplified in the obesity and hypertension data. CARDIA¹ documented 30% and 65% reductions in the development of obesity and hypertension respectively in young overweight adults; Zemel et al³⁴ reported >80% difference in obesity rates between those Americans in the lowest quartile of dietary calcium intake versus those in the highest quartile. For high blood pressure (BP), observational data indicate that increasing dietary calcium will lower prevalence by 30% to 40% in the general adult population, whereas intervention trials in pregnant women at risk of hypertensive disorders have demonstrated as much as an 80% reduction in risk.^{28,35}

Obesity

In a recent randomized controlled trial, Zemel et al³⁶ confirmed their earlier clinical and observational findings³⁴ that dairy product intake significantly accelerated weight and fat loss. These findings are consistent with the CARDIA study,¹ which provided evidence of a benefit from increased dairy food intake on obesity incidence over a 10-year period. That study documented a 30% reduction in the emergence of obesity in young overweight adults. Similarly, Heaney et al³ projected that dietary calcium

Table 3. Estimated 1-year and 5-year healthcare cost savings

Disorder	1st Year		5 Year Total	
	Estimated Intervention Effect (%)	\$ (Billions)	Estimated Intervention Effect (%)	\$ (Billions)
Obesity	5	\$2.5	25	\$37.5
Hypertension	40	14	40	70
Stroke	NA	NA	20	20
Coronary artery disease	NA	NA	10	16.5
Type 2 diabetes	5	2.5	25	37.5
Osteoporosis	20	3,5	20	14
Nephrolithiasis	25	0.5	25	2.5
Pregnancy outcomes	25	3.0	25	15
Colorectal cancer	NA	NA	5	0.75
Total		\$26		\$209

intake >1200 mg/d was associated with a nearly fivefold reduction in the proportion of individuals with body mass index (BMI) >26 kg/m², compared to those consuming <500 mg of dietary calcium/d, and that increased intake across the population could reduce overweight and obesity prevalence by 60% to 80%.³⁷ These estimates are congruent with the National Health and Nutrition Survey (NHANES) data analyses of Zemel et al,³⁴ and consistent with recent data from two other longitudinal databases.^{38,39}

In a prospective study of dairy intake and body composition changes in young women, Lin et al⁴⁰ reported that those with higher intakes (1200 to 1400 mg/d) gained less weight and body fat over 2 years than those with intakes <400 mg/d. In their analysis of the NHANES database, Zemel et al³⁴ found a similar reduction in the risk of obesity itself, with persons in the highest calcium intake quartile having one-sixth the risk of being obese compared with those in the lowest intake quartile. Melanson et al⁴¹ have recently shown, using whole body, indirect calorimetry, that high calcium intake promotes fat oxidation, as was also found by Zemel et al in their animal model.³⁴

On the basis of these data, we estimate that increasing dairy food intake to recommended levels would be associated with an annual reduction of 5% in the incidence of obesity in Americans, increasing by an additional 5% per year, yielding a 25% reduction at 5 years. Using that estimate of impact, 1-year healthcare savings would approach \$2.5 billion and at 5 years would exceed \$37.5 billion.

Hypertension

Findings from the first DASH trial^{9,42} and estimates from observational data^{30,43} suggest that the incidence of hypertension requiring drug therapy would decrease 35% to 70% with the introduction of a diet containing 3 to 4 daily servings of dairy foods. Analysis of the first NHANES⁴³ indicated that a dietary calcium intake >1000 mg was associated with a 40% to 50% reduction in hypertension prevalence, consistent with DASH findings.⁴² The CARDIA study documented an approximate 65% reduction in the emergence of hypertension with similar dairy intake over 10 years.1 The DASH trial demonstrated that reductions in BP occur within 2 weeks and are sustainable.9 As indicated by National Heart, Lung, and Blood Institute (NHLBI) in the most recent report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7), the DASH diet is more effective than the longstanding recommendation regarding sodium reduction.44

On the basis of these collective observations, we project a virtually immediate 40% reduction in the prevalence of mild-to-moderate hypertension with an increase in dairy product intake to 3 to 4 servings/d. First-year healthcare cost savings would approach \$14 billion, and be

sustained for a cumulative savings at 5 years of \$70 billion.

Coronary Artery Disease and Stroke

On the basis of the BP reductions observed with the first DASH trial, NHLBI and the DASH investigators estimated that coronary artery disease (CAD) incidence would decrease by 15% and stroke by 27%, although no time frame was given. We have assumed no savings in the first 2 years, but project annual improvements in CAD incidence of 10% and stroke of 20% beginning in year 3, resulting in 5-year cost savings of \$16.5 billion and \$20 billion, respectively. Given the >40% reduction in stroke and 30% reduction in cardiovascular disease documented by Kant et al, these estimates for CAD and stroke appear reasonable.

Type 2 Diabetes

Two recent RCTs of lifestyle and diet improvements for the prevention of type 2 diabetes documented 60% reductions in risk. Both used low fat dairy foods as a component of the dietary interventions. The CARDIA study demonstrated that the incidence of abnormal glucose tolerance was decreased 50% over 10 years.

On the basis of these figures, we estimate that the introduction of a diet containing 3 to 4 servings/d of dairy foods would produce a 5% annual reduction in new cases of type 2 diabetes with a 5-year reduction of 25%, resulting in first-year savings of \$2.5 billion and 5-year savings of \$37.5 billion.

Osteoporosis

Higher calcium intake, often specifically from dairy foods, and in conjunction with normalization of vitamin D status, has been conclusively shown to augment bone gain during growth⁴⁷ and to slow age-related bone loss and fracture rate.⁴⁸ Optimal calcium intake has been recommended for protection of bone mass by three NIH Consensus Development Conferences 16,49,50 and in the most recent recommendations of the Institute of Medicine.⁵¹ At least four randomized controlled trials have shown significant fracture reduction with augmented calcium intake. 52-55 Using a combination of calcium, phosphorus, and vitamin D (three of the nutrients for which milk is a principal source), Chapuy et al⁵² reported ~40% reduction in hip and other extremity fractures within 18 months. Dawson-Hughes et al⁵³ found a 55% reduction in nonvertebral fractures by 3 years of supplementation with calcium and vitamin D. Heikinheimo et al⁵⁶ used supplemental vitamin D alone in a population with a high average calcium intake, and observed a 25% reduction in nonvertebral fractures over a 4.5-year intervention.

Less well attested are the skeletal benefits attributable to other dairy nutrients. Potassium, for which milk is a primary source, has been shown to be associated with augmented adult bone mass,^{57,58} possibly because this

cation reduces urinary calcium loss.^{59,60} Protein, a putatively negative factor at low calcium intakes,^{61,62} has been shown to be synergistic with calcium, reducing age-related bone loss in most,^{31,63} but not all⁶⁴ studies. In fact, protein has been shown to be a necessary co-factor for the skeleton to realize the benefit of high calcium intake.^{31,62,65}

As noted, point estimates for fracture reduction as high as 55% have been reported. However, the confidence intervals around these estimates are broad, and data for vertebral fracture prevention by calcium or diet are sparse. For purposes of this analysis, we took a conservative estimate, ie, a 20% reduction in fracture risk related to dairy intakes that provide, with other food calcium sources, 1000 to 1500 mg of calcium/d. Direct costs for all osteoporotic fractures combined were estimated to be \$17 billion for 2002.²² A 20% reduction translates to \$3.5 billion savings each year, achievable by year 2 of the higher intake, reaching cumulative savings of \$14 billion by year 5.

Nephrolithiasis

In a recent 5-year randomized trial comparing two diets in men with recurrent stones, Borghi et al⁶⁶ found that those consuming the higher calcium diet (1200 mg/d) compared to those on low calcium (400 mg/d) had a 50% reduction in recurrence risk. Similarly, two large-scale prospective studies both estimated an approximate 50% relative risk reduction in the occurrence of renal stones in women and men between the lowest and highest quartiles of dietary calcium intake.^{67,68}

We conservatively estimate a 25% reduction in stone incidence from years 1 through 5. On the basis of 1995 estimated yearly costs of \$2 billion, we project savings in the first year of \$0.5 billion and \$2.5 billion over the 5-year interval with dairy food intake of 3 to 4 servings/d in at-risk individuals.

Outcomes of Pregnancy

The observational data^{69,70} and most,^{27,35} but not all⁷¹ randomized controlled trials of pregnancy-induced hypertension (PIH) or preeclampsia consistently indicate that 50% to 80% of cases could be eliminated if dietary calcium intake were sufficient to meet the mineral demands of gestation. The quantity of dietary calcium appears to be at least 1200 mg/d, 69,72 and the association has been specifically tied to prior dairy food intake, 70,72 ie, where dietary calcium intake before pregnancy is low, PIH is more likely to develop. The outcome of the Calcium for Preeclampsia Prevention trial in which the mean calcium intake at baseline for both the intervention and placebo groups was well above typical intakes among women in this age group demonstrated the reverse. The reduction in PIH incidence in these healthy pregnant women with a mean calcium intake of 1200 mg/d approached but did not achieve statistical significance.

The major healthcare expenditures of this condition

relate to premature delivery, resulting in preterm and low birth weight infants.²⁴ Costs are greatest for infants born between 32 and 36 weeks gestation,²⁴ the time frame in which PIH typically necessitates early delivery. An estimated 25% reduction in these conditions would result in cost savings of \$3 billion in the first year, and \$15 billion at year 5.

Colorectal Cancer

In an RCT in persons at risk for colonic neoplasia, use of dairy products to provide up to 1200 mg of calcium/d resulted in decreased colonic epithelial cell proliferation and improved markers of normal cellular differentiation.73 The Calcium Polyp Prevention Study⁷⁴ assessed effects of calcium carbonate (1200 mg of calcium/d) in people with histories of colorectal adenomas, and observed a significant, although moderate reduction in the risk of recurrent colorectal adenomas. Recent observational studies have reported significant inverse associations between calcium intake, including dairy products, and colon cancer risk.75-77 We based our estimate of cost savings on observational data that indicate a significant reduction in colorectal cancer where dietary calcium intake is higher with the RCTs that primarily assessed dietary calcium's effects on epithelial cell proliferative changes as a percursor for neoplastic transformation.

Colorectal cancer savings have been projected at 3 through 5 years, as no human data exist to suggest a more immediate effect. On the basis of RCTs^{73,74,78,79} and observational data,^{75,76} we estimate a 5% annual reduction in cases beginning in year 3 with a cumulative 5-year savings of approximately \$0.75 billion. This estimate does not account for the costs of colorectal polyps that may equal those for colorectal cancer and for which the intervention data ascribe a significant reduction in risk with increasing dairy consumption.^{73,74}

Aggregate Savings

Using conservative estimates of impact, we project that combined first-year healthcare cost savings for these disorders would exceed \$26 billion and yield 5-year cumulative savings of approximately \$209 billion with daily intakes of 3 to 4 servings of dairy foods (Table 3). First-year savings represent a 10% reduction in total costs for the conditions considered and over 5 years represent a >15% cost savings. Although these estimates are based on total population dietary adjustments, improvement in dairy consumption would need to be achieved in only a modest percentage of the adult population, all of which is at risk for one or more common medical conditions, for the healthcare system to begin realizing these savings.

It might seem counterintuitive that a factor that explains only a small percentage of the variance of an outcome could produce an appreciable effect when implemented at a population level. However, as Rose and Day⁸⁰ have pointed out, small shifts in the mean of a distribution will

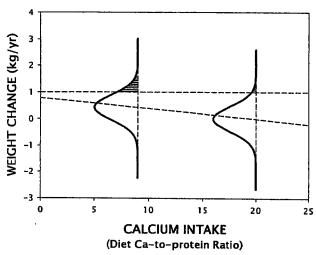


FIG. 1. Plot of the regression line relating dietary calcium (Ca): protein ratio to weight gain in midlife women, from the data of Davies et al. ⁸¹ Superimposed on this regression line are plots of the normal distribution with means at predicted weight gain for calcium: protein ratios of 9 and 20 mg of calcium:gram of protein, and with standard deviations equal to the standard error of the estimate for the regression. The areas under the two curves for weight gain ≥ 1 kg/year (the horizontal dashed line) are shaded. (Copyright Robert P. Heaney, 2002, used with permission.)

inevitably be associated with large changes in the proportion of a population that may lie above or below any given external reference point. Diseases such as hypertension and obesity are, in fact, defined precisely with respect to such external reference points (ie, BP, BMI).

Fig. 1 illustrates that point for the data set of Davies et al⁸¹) describing the relationship between midlife weight gain in women and calcium intake, in which calcium intake explained approximately 3% of the variance in weight change. Using a weight gain of ≥1 kg/year as the index outcome, at a calcium-to-protein ratio of 9.0, 15.4% of the women in this cohort were gaining weight at a rate of >1 kg/year, whereas at a calcium-to-protein ratio of 20 (approximately the recommended calcium intake), ⁶³ that fraction was reduced to less than 4%, a 76% reduction (Fig. 1). Any such analysis assumes homoscedasticity of the data around the regression line, and assumes that such a relationship, found in observational data, would be obtained in an interventional study as well.

In this assessment, we have very conservatively estimated the healthcare cost savings that might be achieved if our society increased per capita dairy consumption to levels closer to those that existed 50 years ago⁸² and consistent with current National Academy of Sciences nutrient recommendations for adults. Because of the acknowledged limitations of this assessment, we have chosen to underestimate the impact and actual savings that would likely be realized. We have not included typical indirect costs or projected long-term savings, which for many of these conditions would greatly exceed the \$209

billion in direct cost savings during the 5 years we have estimated.

The notion that healthcare savings would be potentially immediate may seem counter to the time frame in which we have previously viewed health effects of dietary calcium and dairy food intake. Whereas the benefits of dairy food consumption early in life were often associated with skeletal health many years later, we now know that benefits for bone health 52,53,83 and other conditions may be evident within only a few months or years. 1,9,18 Furthermore, even for bone health they are not restricted to older persons, as even in adolescents, fracture risk is inversely related to bone mass. 84

In setting out projections of healthcare savings potentially achievable by increased dairy consumption, it is understood that other dietary components also contribute to improved health and are not to be diminished in their importance. Our focus on dairy is based on the accumulated data from the past two decades that specifically link that food group or certain of its major components, to a variety of diseases to a degree as yet not documented for other major components of the diet. In fact, as a number of studies have documented over the years, individuals whose diets include adequate levels of dairy products generally consume a higher quality diet overall, comprising most of the components believed to be beneficial for disease prevention and management. 1,18,43,85 Some of this apparent effect may be because dairy intake reflects a generally healthy lifestyle, but some is clearly due to a direct effect of the dairy nutrient profile on diet quality. In a secondary analysis of diets in their 1992 report, 84 Barger-Lux et al noted that as little as one additional serving of milk a day would have moved most participants with poor quality diets into a status of dietary adequacy.

Several additional medical disorders, primarily related to women's health, were considered in terms of dairy intake, but not included in this assessment because published data were not sufficient to allow reasonable projection of healthcare savings. These include breast cancer, ^{86–88} premenstrual syndrome, ^{89–92} and postpartum depression. ⁹³ For each of these conditions, available data suggest that risk might be reduced by up to 50% where either dairy or calcium intake is sufficient, consistent with the effect size for the other disorders addressed here.

Offset Savings?

If there were costs of illness directly attributable to higher dairy food consumption, these would offset the healthcare savings described here. We considered that outcome in our assessment. Associations have been postulated between increased dairy food intake and the risk of CAD, obesity, kidney stones, type 2 diabetes, and prostate cancer. The evidence, as reviewed, points in the opposite direction.

Despite allegations that because of their saturated fat content, dairy foods cause heart disease, there is no definitive evidence to support this association. 94,95 There are,

however, data to refute it. In a 25-year prospective study of 6000 adult men in Scotland, higher milk consumption was found to be associated with reduced cardiovascular mortality. We have not found any study that specifically links dairy products with increased cardiovascular disease or mortality. Whether dairy foods constitute an exception or whether the risk of saturated fat has been exaggerated⁶ is unclear. It is known that individuals with higher dairy intakes do not have higher total fat intakes than other individuals, 85,96,97 likely indicating substitution of dairy fat for other fat sources. The CARDIA study provides compelling evidence against higher risk of either coronary artery disease or obesity with increased dairy intake, and is supported by the reports by Kant et al¹⁸ and Zemel et al^{34,36} associating adequate dairy food intake with lower cardiovascular disease and cancer, and obesity risk, respectively. Finally, as noted, the first head-to-head RCT comparisons of low versus normal-fat weight loss diets also suggest no benefits in terms of CVD risk factors of the lower fat diets.^{7,8}

The purported association between milk consumption and increased prostate cancer risk is countered by several facts. Giovannucci and colleagues, who have previously reported this putative association in several observational studies, 98,99 have recently demonstrated by multivariate analysis that dairy foods are not directly associated with increased risk of prostate cancer development. 100 Furthermore, African American men, who have the lowest milk intake among male US population groups, also have the highest prostate cancer rates. Most notably, the only RCT addressing this question indicates that high calcium intake actually lowers the risk of prostate cancer. 101

In the case of kidney stones lies perhaps the best example of a putative association between dairy intake and a common disorder that has been refuted by both observational studies and controlled clinical trials. These studies have dispelled the prior assumption that high calcium intake increases risk. As reflected in recent treatment guidelines, 12 these data indicate that higher calcium intake is an important prerequisite for lowering kidney stone risk, 67,68 rather than increasing it, as previously assumed in the absence of scientific evidence.

Conclusion

The contention that health and cost benefits would ensue from improved dairy intake may strike many as improbable, given the focus of our nation's nutrition initiatives during the past 40 to 50 years. These have typically recommended limiting dairy intake to 2 to 3 servings/d and to only low fat or no fat varieties, ^{12,102} based on the hypothesis that dairy fat is a major contributor to heart disease. This presumption was formerly ingrained in dietary recommendations from federal and voluntary health organizations, several of which are now being revised in light of new data. ^{103–105} The recent acknowledgment by NHLBI in JNC 7 that the DASH diet is more effective than

sodium restriction is an excellent example of that transition 44

Many of the studies that initially suggested dairy intake was a factor in reducing the risk of developing one or more of these conditions^{30,43,105} did so based on an identified association of higher dietary calcium with risk reduction, and overlooked the likelihood that calcium serves as a marker for dairy foods.^{27,30,43,105,106} Beneficial effects of the full nutritional profile of dairy foods, which includes many minerals, proteins, vitamins, specific carbohydrates, and essential fatty acids, were demonstrated in the CARDIA study¹ in which it was not dairy calcium, but dairy *foods* (including butter and ice cream) that were associated with the reduction in multiple coronary risk factors. This same point was recently highlighted by NICHD investigators with regard to possible benefits of dairy foods on body weight.¹⁰

Although promotion of the DASH trial has tended to emphasize the nondairy components of the DASH diet, 9,11 that focus is not consistent with analyses done to identify the specific predictors of the observed BP decreases. Karanja et al 107 noted that improvements in calcium, phosphorus, potassium balance, and vitamin D status tracked most directly with BP reductions. This finding is consistent with another comprehensive nutrition trial that reported comparable improvements in BP and identified essentially the same metabolic profile. 108 In addition, it was only the DASH combination diet, containing dairy, that also increased folate levels and decreased homocysteine levels. 109

An important objective of this evaluation was to consolidate a disparate body of data. It is our expectation that this analysis will provide a more precise focus for a public health nutrition strategy directed at the escalating health-care costs for these disorders. Even if our conservative projections have overestimated savings by a factor of 2 or 3, the benefit to society would still be substantial.

In contrast to current recommendations that provide broad nutrition guidance aimed at assuring general good health, the public health strategy that could emerge from this analysis would be simple and focused: 3 to 4 servings of dairy foods/d. The message is applicable to several major health concerns of adults today: weight, hypertension, type 2 diabetes, and heart disease, and builds on the well-established benefit of dietary calcium for bone health. Furthermore, only marginal expenditure of resources would be required to implement this public health initiative. Because of the likelihood of immediate healthcare savings, the actual effectiveness of such a public health nutrition strategy would be verifiable within 5 to 10 years.

We anticipate some skepticism and even resistance to this assessment of the healthcare savings that could be achieved by reversing the decades-long decline in dairy food intake in the US. If it provokes a healthy debate among experts, we will have achieved our purpose. By focusing attention on the present opportunity to improve the health of virtually all members of our society and dramatically reducing skyrocketing healthcare costs, we are confident that a national initiative can emerge to turn this opportunity into reality.

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